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ROBUST SUMMARY
OF INFORMATION ON

Substance Group

LUBRICATING OIL BASESTOCKS

Summary prepared by American Petroleum Institute

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NB. Reliability of data included in this summary has been assessed using the approach described by Klimisch et al.

Klimisch, H. J., Andreae, M. and Tillman, U, (1997)
A systematic approach for evaluating the quality of experimental toxicological and ecotoxicological data.
Regulatory Toxicology and Pharmacology 25, 1-5.

1.1.1 GENERAL SUBSTANCE INFORMATION

Substance type : Petroleum product
Physical status : Liquid

Remark : The group of base oils consists of products that are derived from both distillates and residues of the vacuum distillation process in petroleum refining.

Base oils consist predominantly of hydrocarbons but may also contain small quantities of sulfur and nitrogen compounds with traces of a number of metals. The oils contain complex hydrocarbons with variable mixtures of paraffins, naphthenes and aromatics with carbon numbers in the range 15 to 50. Hydrocarbon constituents derived from vacuum distillates boil generally in the range 300 to 600 °C, whereas those derived from residual oils may boil up to 800 °C.

Unrefined vacuum distillates contain polycyclic aromatic compounds (PACs) which are removed during any subsequent refining process. The more severe the refining, the lower the PAC content will be of the refined base oil.

Physical chemical data for a range of base oils have been summarized by CONCAWE and these are tabulated in the attached document.

For most of the mammalian toxicology endpoints, information has been used that was derived by the American Petroleum Institute on a wide range of base oils. For simplicity, this robust summary contains detailed information on an API sample of an unrefined distillate (high PAC) and an API sample of a highly refined distillate (low PAC). If data was available on other samples, it has either been summarized in tabular form in the relevant sections of this summary or discussed in detail when appropriate.

The API sample of highly refined base oil for which data have
been selected is one with a low average molecular weight since this is likely to represent the worst case from a toxicological perspective.

The physico-chemical characteristics of the two samples are as follows:

	Method	Unrefined oil	Highly refined oil
API sample No.		84-01	83-12
CAS No.		64741-50-0	64742-53-6
API Gravity @60°	D287	31.9	25.9
Density @15°C	D287	0.8651	0.8981
Molecular wt. (gm/mol)	D2224	300	260

Refractive index (RI units @20 °C)		1.4815	1.4910
Total Sulfur (wt. %)	D3120	0.38	0.04
Total Nitrogen (ppm/wt)	Chemil	210	38
Total oxygen (wt.%)	NAA	0.038	0.077
Total Chloride (ppm/wt)	coulom	11	2
Viscosity (cSt @ 40°C)	D445	14.07	0.44
Viscosity (cSt @ 100°C)	D445	2.79	2.14
Pour point (°F)	D93	+60	<-20
Carbon residue (wt. %)	D524	0.15	0.14
Distillation	D1160		
IBP (°F)		595	450
FBP (°F)		810	785
Hydrocarbon type analysis			
Nonaromatics (wt. %)	D2549	79.1	67.3
Aromatics (wt. %)	D2549	20.9	31.9
	TOTAL	100	100

Some oils are destined for food use or pharmaceutical applications and for these the refining process that they undergo is particularly severe to ensure that aromatic materials have been removed and that the resulting oil is colorless. Such oils are known as white oils. Unlike the other base oils in which oral intake is unintentional, the white oils are intended for uses in which an oral intake is likely. For these materials, oral studies are available and, where appropriate, are included in this Robust Summary.

Several individual companies have generated data on environmental effects and ecotoxicity. The relevant CAS descriptions of the materials that have been tested are included in the relevant sections of this robust summary.

Attached document : See Attachment 1. Physico-chemical Properties for Selected Lubricating Oil Basestocks

(71)

1.8.1 OCCUPATIONAL EXPOSURE LIMIT VALUES

Type of limit : TLV (US)
Limit value : 5 mg/m^3
Short term exposure limit value
Limit value : 10 mg/m^3

Remark : A TWA TLV of 0.005 mg/m^3 is proposed for the sum total of 15 polynuclear aromatic hydrocarbons (PAHs) listed as carcinogens by the U.S. National Toxicology Program (NTP).

(1)

1.13 REVIEWS

Memo : IARC reviewed, in 1984, the carcinogenicity information on lubricating base oils and the outcome of their review was published in a Monograph.

(89)

Memo : Bingham reviewed the literature for information on the carcinogenic potential of petroleum hydrocarbons. This review contained information on base oils.

(21)

Memo : CONCAWE demonstrated that it was possible to distinguish between carcinogenic and non-carcinogenic base oils on the basis of the level of DMSO extractables. This approach was subsequently adopted in the EU for classification purposes.

Remark : The DMSO method was adopted subsequently in the EU to distinguish between carcinogenic and non-carcinogenic oils for classification and labeling purposes.

(70) (75)

Memo : The EU Scientific Committee for Food (SCF) and the WHO Joint Expert Committee on Food Additives (JECFA) have reviewed the available data on the toxicology of mineral hydrocarbons for food uses.

(90) (99)

Memo : The WHO published an Environmental Health Criteria document which included summarized information on lubricating base oil stocks

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2.1 MELTING POINT

Method : ASTM D97
GLP : No data
Test substance : Lubricating Base Oils; distillate oils, residual oils, and white oils various

Remark : By definition, melting point is the temperature at which a solid becomes a liquid at normal atmospheric pressure. For complex mixtures like petroleum products, melting point may be characterized by a range of temperatures reflecting the melting points of the individual components. To better describe phase or flow characteristics of petroleum products, the pour point is routinely used. The pour point is the lowest temperature at which movement of the test specimen is observed under prescribed conditions of the test (ASTM 2002). In addition, the pour point methodology defines a "no-flow" point, defined as the temperature of the test specimen at which a wax crystal structure or viscosity increase, or both, impedes movement of the surface of the test specimen under the conditions of the test (ASTM 2002). Because not all petroleum products contain wax in their composition, the pour point determination encompasses either change in physical state (i.e., crystal formation) and/or viscosity property.

Result :

Oil type	Pour Point, °C
Distillate oils	
Solvent de-waxed, light paraffinic (CAS No. 64742-56-9)	-18
Solvent de-waxed, heavy paraffinic (CAS No. 64742-65-0)	-12
Hydrotreated, light paraffinic (CAS No. 64742-55-8)	-18
Hydrotreated, heavy paraffinic (CAS No. 64742-54-7)	-9
Hydrotreated, light naphthenic (CAS No. 64742-53-6)	-60
Hydrotreated, heavy naphthenic (CAS No. 64742-52-5)	-24
While mineral oil (CAS No. 8042-47-5)	-15
Residual Oils	
Solvent de-waxed (CAS No. 64742-62-7)	-6

Reliability : (2) Valid with restrictions
Results of standard method testing were reported in a reliable review dossier.

(16) (17) (71)

2.2 BOILING POINT

Method : Calculated by: MPBPWIN V1.40 (EPIWIN V3.10; US EPA 2000)
GLP : No
Test substance : American Society for Testing and Materials (ASTM). 2002. Standard Test Method for Pour Point of Petroleum Products (Rotational Method). ASTM D5985-02, Volume 05.01, ASTM, West Conshohocken, PA.

Remark : The substances covered in lubricating base oils are complex and variable mixtures of paraffins, naphthenes (cycloparaffins), and aromatics having carbon numbers ranging from about 15 to 50. Because they are mixtures, lubricating base oils do not have a single numerical value for boiling point, but rather a boiling range that reflects the individual components. Base oils are produced from vacuum distillation of the residue obtained after the atmospheric distillation of crude oil. The vacuum distillates and the vacuum residues together form the general group of unrefined or mildly refined base oil. Additional treatments or refinements such as solvent extraction, dewaxing, and hydrogenation, are employed to produce oils with desirable properties. The ranges of components modeled using MPBPWIN V1.40 are given in the table above. Those values are consistent with information provided by CONCAWE (1997) that indicated component hydrocarbons of oils produced from vacuum distillation have boiling points ranging from 300 to 600°C whereas those produced from vacuum residues contain components with boiling points as high as 800°C (CONCAWE 1997).

Result : See Remarks Section
Calculated Boiling Point Ranges, °C:

C_{15} to C_{50} Paraffinic:	250 to 682
C_{15} to C_{50} Naphthenic:	282 to 683
C_{15} TO C_{50} Aromatic:	312 to 788

Reliability : (2) Valid with restrictions

(71) (110)

2.4 VAPOUR PRESSURE

Method : Directive 84/449/EEC, A.4 "Vapour pressure"
Year : 1991
GLP : Yes
Test substance : CAS No. 64742-65-0, Distillates (petroleum), solvent-dewaxed heavy paraffinic

Result : Three runs on the sample were conducted. There was initially substantial reduction (equivalent to 3°C temperature change) of estimated VP on prolonged pumping after Run 1 but this was reduced to the equivalent of 0.65°C change between Runs

2 and 3. The latter runs provided values at room temperature of 1.882 and 1.563 x 10^{-4} Pascals, yielding a mean value of Vp (298.15K) = 1.723 x 10^{-4} Pascals. The condensation rates onto the pan observed in Run 3 increased with temperature more rapidly than the mass difference indicating an increasing efficiency of condensation and thus precluding the use of the condensation data to produce a satisfactory VP relation. The final values of rate of condensation were however equivalent in pressure regime to the mass differences assuming a rough equality between the numerical magnitudes of temperature and molar mass.

Test condition : The vapor pressure (VP) was determined using a VP balance based on a CI Electronics micro-balance with a sensitivity of approximately 0.1 mg. Sample temperature was controlled electronically (±1°C) over the range from ambient to 250°C. Mass readings and temperature were recorded directly onto a 2-channel chart recorder. The VP balance was designed such that on opening the slide across the orifice in the temperature controlled evaporation furnace, the escaping vapor jet was directed at the scale pan. VP was determined directly from the pressure on the scale pan by measuring the difference of mass readings when the slide across the orifice was open and closed. When condensation occurred onto the pan the VP can be calculated from the condensation rate if the molar mass is known. VP of the sample was measured at several temperatures to yield VP curves for subsequent extrapolation to give 298.15K values. Slope and intercept of VP curve were estimated by an unweighted least squares statistical treatment of the data and errors are ± standard deviation of the respective quantity. Maximum and minimum values of VP at 298.15K were calculated directly from the VP relationship using the ranges of errors in slope and intercept respectively. The quoted errors in VP at 298.15K were then calculated directly by extrapolation from these values.

Reliability : (1) Valid without restriction

(88)

3.1.1 PHOTODEGRADATION

Method	:	Calculations by EPIWIN V3.10; AOPWIN V1.90.
Year	:	2001
GLP	:	No
Test substance	:	CAS No.: Various; Unrefined and acid treated base oils.
Remark	:	AOPWIN V1.90 calculates atmospheric oxidation half lives of hydrocarbons in contact with hydroxyl radicals in the troposphere, under the influence of sunlight. Atmospheric oxidation rates were calculated for the lowest molecular weight constituents, i.e., C_{15} hydrocarbon components. Although the low vapor pressures of these base oils indicate that volatilization will not be a very significant fate process, oxidation half-lives indicate this may be a moderate removal process if these substances were introduced to the atmosphere by adsorption to particulate matter via atmospheric emissions. The half-lives for degradation of these hydrocarbons by reaction with hydroxyl radicals, in the troposphere, under the influence of sunlight, will all be less than one day, by extrapolation from the data quoted by Atkinson (1990). In general, most products in the base oil category do not contain component molecules that will undergo direct photolysis. Saturated hydrocarbons (paraffins and naphthenics), and single ring aromatics, which constitute the majority of these components, do not absorb appreciable light energy above 290 nm. Therefore, direct photolysis will not contribute to a measurable degradative removal of chemical components in this category from the environment.
Result	:	Indirect photolysis at 25 °C Concentration of sensitizer: 1.50 x 10^{6} OH radicals/cm^3 Rate constant: 18.1757 x 10^{-12} cm^3/mol-sec Half-life: 0.053 - 0.66 days for C15 hydrocarbon constituents
Reliability	:	(2) Valid with restrictions The predicted endpoint was determined using a validated computer model.

(19) (72) (109)

3.1.2 STABILITY IN WATER

GLP	:	No
Result	:	Measured value: N/A Degradation %: N/A Half-life: N/A Breakdown products: N/A
Conclusion	:	Hydrolysis of an organic chemical is the transformation process in which a water molecule or hydroxide ion reacts to form a new carbon-oxygen bond. Chemicals that have a potential to hydrolyze include alkylhalides, amides,

carbamates, carboxylic acid esters and lactones, epoxides, phosphate esters, and sulfonic acid esters. The chemical components that comprise the base oil category are hydrocarbons, which are not included in these chemical groups, and they are not subject to hydrolysis reactions with water.

Reliability : (1) Valid without restriction

(87)

3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

Type : Mathematical computer model
Media : Soil, air, water, suspended sediment and sediment for C15 hydrocarbon structures
Method : Calculations by EQC V2.11
Year : 1999

Remark : Model based on chemical fugacity. Multimedia distribution was calculated for C_{15} hydrocarbons, the lowest molecular components found in base oils. Larger molecular weight components are expected to exhibit greater partitioning behavior to terrestrial media. Mobility in the aquatic and atmospheric environment is low due to low water solubility and low vapor pressure. These components will partition rapidly to the terrestrial compartment, where the main fate process is expected to be slow biodegradation of base oil components in soil and sediment.

A summary of the EQC modeling of the distribution and transport between environmental compartments for selected hydrocarbon compounds in lubricant base oils is presented in the attached table and graph. The compounds selected for modeling represent various C_{15} compounds in base oils (e.g., linear and branched paraffins, naphthenes and aromatic hydrocarbons).

Result :

Medium	% distribution
Air:	0 to 94
Soil:	6 to 97
Water:	0.88 to <0.0001
Sediment	<0.1 to 2
Suspended Sediment	<0.02 to 0.004

Attached document : See Attachment 2. EQC Modeling Results of the Distribution Between Environmental Compartments

See Attachment 3. Plot of the EQC Modeling Results of the Distribution Between Environmental Compartments

Conclusion : This complex petroleum mixture is expected to partition primarily to soil and/or sediment.

Reliability : (2) Valid with restrictions
The predicted endpoint was determined using a validated computer model.

(72) (107)

3.5 BIODEGRADATION

Type : Aerobic
Inoculum : Microorganisms were obtained from Canterbury Sewage Works (UK) and prepared according to the prescribed methods for this test.
Contact time : 28 day(s)
Method : Directive 84/449/EEC, C.5 "Biotic degradation - modified Sturm test"
Year : 1986
GLP : Yes
Test substance : CAS No. 64742-65-0; Distillates (petroleum), solvent-dewaxed heavy paraffinic

Result : The test substance was partially degraded to 20-26% of the theoretical CO_2 in 28 days. Degradation commenced after a lag period of 2 days. Biodegradation curve showed that degradation had virtually stopped by day 28. Test substance was therefore inherently biodegradable since it achieved >20% biodegradability based upon CO_2 evolution.

Sample	% Degradation (day 28)	Mean % Degraded
Test substance	26, 20	23
Na Benzoate	86, 92	89

Test condition : The test substance was added to test medium from a stock solution containing 2.4 g/l emulsified in Dobane PT sulphonate (2 mg/l), a non-biodegradable detergent. The final test concentration of the base oil was 20 mg/l. The test medium was dispensed into Sturm vessels, inoculated and aerated with 60 ml/min of CO_2-free air and incubated at 20 ± 1°C. Biodegradation was determined on days 1, 2, 5, 9, 14, 20, and 28 by titrating the total CO_2 released. The medium was acidified on day 27 to release the total CO_2 by day 28. Test substance, control blank, and sodium benzoate control (20 mg/l) were tested in duplicates. The empirical formula used was C_nH_{2n+1} which yielded a theoretical CO_2 evolution of 3.14 g CO_2 per g of test substance.
Reliability : (2) Valid with restrictions
The study report lacked an extensive description of experimental procedures but instead referenced procedures detailed in a laboratory SOP.

(102)

Type : Aerobic
Inoculum : Activated sludge, domestic
Contact time : 28 day(s)
Method : OECD Guide-line 301 F "Ready Biodegradability: Manometric Respirometry Test"
Year : 1995
GLP : Yes
Test substance : CAS No. 64742-54-7; Distillates (petroleum), hydrotreated heavy paraffinic

Result : By day 28, 31% degradation of the test material was observed and indicated that the test material was inherently biodegradable.
By day 5, >60% biodegradation of positive control was observed, which meets the guideline requirement. No excursions from the protocol were noted.

Biodegradation was based on net oxygen consumption and the theoretical oxygen demand of the test material as calculated using results of an elemental analysis of the test material.

Sample	% Degradation* (day 28)	Mean % Degradation (day 28)
HHP	32.93, 27.2,33.27	31.13
Na Benzoate	82.04; 72.88	77.46

* replicate data

Test condition : Fresh activated sludge was obtained one day prior to test initiation, and homogenized in a blender for two minutes. After allowing the sample to settle for approximately 30 minutes, the homogenated supernatant was decanted, avoiding carry-over of solids. Microbial activity of an aliquot of the filtered supernatant was $1E^6$ CFU/ml which was determined using microbial agar dip slides. Activated sludge supernatant was added to the test medium at 10 ml/l and the inoculated medium was continuously aerated with CO_2-free air until the next day when the test systems were prepared. Test medium consisted of glass distilled water and mineral salts (phosphate buffer, ferric chloride, magnesium sulfate, calcium chloride). Test vessels were 1 Liter glass flasks located in a water bath and electronically monitored for oxygen consumption. Test material was tested in triplicate, controls and blanks were tested in duplicate. Test material (hydrotreated heavy paraffinic petroleum distillates, HHP) concentration was approximately 44 mg/l, equivalent to a theoretical oxygen demand (ThOD) of 148 mg/l. Test material was weighed onto a Gelman type A/E 13 mm glass fiber filter which was then added to each respirometer flask. Sodium benzoate (positive control) concentration was 53.54 mg/l, and was added using an aliquot of a stock solution. Test temperature was 22 ± 1°C. All test vessels were stirred constantly for 28 days using magnetic stir bars and plates.

Reliability : (1) Valid without restriction

(83)

Type : Aerobic
Inoculum : Activated sludge, domestic
Contact time : 28 day(s)
Method : OECD Guide-line 301 B "Ready Biodegradability: Modified Sturm Test (CO2 evolution)"
Year : 1990
GLP : Yes
Test substance : CAS No. 64741-89-5; distillates (petroleum), solvent-refined, light paraffinic

Result : By day 28, the 10 and 20 mg C/l test flasks showed biodegradation of 29% and 22%, respectively.

Day	% Degradation Reference	% Degradation 10 ppm Test Sub.	% Degradation 20 ppm Test Sub.
10	31	0	1
21	89	25	12
28	89	29	22

The test material was not readily biodegradable. Within a

period of 28 days, 22 and 29% degradation was observed. The pass limit for this test is 60% within 28 days.

The reference test substance was degraded to 89% by day 28. The pH of the test cultures (10 mg/l and 20 mg/l) and controls (sodium benzoate standard and negative control) measured on Day 27 were 4.8, 4.8, 4.9, and 5.2, respectively.

Test condition : The test material entered the experimental containers through direct dispersion in water. Activated sludge bacteria from the Severn Trent Plc sewage treatment plant in Belper, Derbyshire was used as the inoculum. The sample sludge was homogenized in a mixer for 10 minutes prior to a solid settling phase and a subsequent filtering of the supernatant for use. The experimental containers had an inoculum concentration of 1%.
The exposures lasted for a period of 28 days. The experimental containers were 5 liter glass culture vessels, containing 3 liters of a mixture of nutrient medium, test material, and inoculum. Test conditions were run in darkness at a constant temperature of 21°C. Nutrient medium was prepared according to the OECD guideline recipe using tap water purified by ion exchange and reverse osmosis.
A series of both two controls and two test material concentrations were run. The controls consisted of a group with just the culture medium and the inoculum and a group with culture medium, inoculum, and 20 mg/l Sodium benzoate (C_6H_5 * COONa). The two test concentrations of test material were 10 and 20 mg/l.
All culture vessels were sealed and aerated with CO_2 free air at a rate of about 2 bubbles per second. Additionally, the solution was continuously stirred by magnetic stirrers.
Samples were taken from the first CO_2 absorber vessel on Days 0, 1, 2, 3, 6, 8, 10, 14, 16, 21, 23, 27, and 28.
Samples were taken from the second absorber vessel on Days 0 and 28. The absorbers were made up of 500 ml Dreschel bottles filled with 350 ml of 0.05M NaOH. The solution was prepared using purified, degassed water. On day 27, the pH of each vessel was measured and 1 ml of concentrated HCl was added to drive off inorganic carbonate. CO_2 production (as inorganic carbon) was measured by an Ionics 555 TOC Analyzer in triplicate.

Reliability : (2) Valid with restrictions
The study was performed following the 1981 guidelines for OECD 301B.

(32)

Type : Aerobic
Inoculum : Activated sludge, domestic
Contact time : 21 day(s)
Method : CEC Method L-33-T-82 using test medium from ISO Standard 7827 and OECD 301A and 301E
Year : 1991
GLP : Yes
Test substance : CAS No. 64741-89-5; distillates (petroleum), solvent-refined, light paraffinic

Result : By day 21, biodegradation of the test substance was 63%, 65%, and 61% in the individual flasks. The mean biodegradation was 63%.

% Biodegradation

	Reference Material			Test Substance		
Day	**Rep1**	**Rep2**	**Rep3**	**Rep1**	**Rep2**	**Rep3**
21	27	29	30	63	65	61
Mean:		29			63	

Biodegradation of the reference material was 27%, 29%, and 30% in the individual flasks, and the mean biodegradation was 29%.
There were no apparent deviations from the given method.

Test condition : Settled activated sludge acquired from Buckland Sewage Treatment Works, Milber, Newton Abbot, Devon, was utilized as the inoculum. The inoculum was normally between 10^5 and 10^7 Colony Forming Units (CFU)/ml. Bacteria were enumerated by Dip Slide (Oxoid, TTC Red Spot) and incubated at 25 ±1°C until sufficient colonies were visible to enable counting.
The inoculum was used in the experiment at a rate of 1 ml per flask.
The test medium was prepared following the formula specified in ISO Standard 7827. Mother solutions of the test substance and reference oil were prepared by adding 150 g of test or reference substance to 1 liter of A113 (1,1,2-trichlorotrifluoroethane). The negative control reference substance was white oil, R.L. 110 (Brixham test substance #T071). The test design consisted of 5 test flasks containing 150 ml of test medium, 1 ml inoculum, and 50 ml of test substance mother solution; 5 reference flasks containing 150 ml of test medium, 1 ml inoculum, and 50 ml of reference substance mother solution; 2 blank flasks containing 150 ml of test medium and 1 ml inoculum; and 1 poisoned flask prepared identical as the test flasks but contained 1 ml of $HgCl_2$. Incubation flasks were 500-ml conical flasks fitted with foam plugs.
On day 0 of the test, two blank flasks, two test flasks, and two reference flasks were sacrificed for analysis of residual oil content by infrared spectrophotometry (see analysis procedure below). The remaining flasks were placed on an orbital incubator and maintained at 25 ± 1°C for 21 days. On day 21, the contents of all flasks were analyzed for residual oil content.

Analysis Procedure:
Residual oil content (%) in each flask was analyzed using a method suitable for the determination of hydrocarbon lubricants in water samples. Lubricants were extracted from water using 1,1,2 trichlorotrifluoroethane and were analyzed using infrared spectrophotometry. The samples were quantified against known standards of the lubricant using the maximum absorption of the CH_3-CH_2 band at 2930 ± 10 cm^{-1}.
Percent test substance degraded was calculated as

$$\frac{\text{\% (ROC) poisoned flask - \% ROC test flask}}{\text{\%ROC poisoned flask}} \times 100$$

Reliability : (2) Valid with restrictions

The CEC method is not a test of ready or inherent biodegradability, nor do the test results provide a reliable measure of the extent of ultimate biodegradability, or mineralization. These test results can only indicate primary biodegradation, i.e., some loss of oil based on concentration analysis of the parent base oil over the course of the study.

(55)

Type : Aerobic
Test substance : Various base oils

Remark : 28 biodegradability studies have been reported for base oils. In the preceding paragraphs a full study description is given for each of the methods that have been used.

Based on the results of ultimate biodegradability tests using modified Sturm and manometric respirometry testing these base oils are expected to be, for the most part, inherently biodegradable.
Results of primary biodegradability testing using the CEC test method indicate that transformation of parent base oil due to biological activity occurs to a varying extent, ranging from 13% to 79% loss of original concentrations of tested base oils.

Summarized data for all studies (including those described in the preceding paragraphs) are tabulated below

Method*	Biodeg. (%)	Biodegradable Yes/No	Ref.
Distillates, solvent-refined heavy paraffinic (64741-88-4)			
OECD 301B**	22, 11	No	30
OECD 301B	15, 12	No	25
OECD 301B	8, 8	No	28
OECD 301B	3, 11	No	29
OECD 301B	12, 11	No	26
OECD 301B	9, 8	No	27
CEC L-33-T-82	72	Yes	57
CEC L-33-T-82	71	Yes	58
CEC L-33-T-82	53	Yes	49
CEC L-33-T-82	79	Yes	50
CEC L-33-T-82	64	Yes	59
CEC L-33-T-82	51	Yes	52
Distillates, solvent-refined light paraffinic (64741-89-5)			
OECD 301B	29, 22	No	32
OECD 301B	17, 17	No	33
CEC L-33-T-82	63	Yes	55
CEC L-33-T-82	75	Yes	56
Solvent de-asphalted Bright stock (64741-95-3)			
OECD 301B	11, 4	No	31
CEC L-33-T-82	17	No	54

Distillates, hydrotreated or solvent refined light naphthenic (64741-97-5)

84\449\EEC, C5	1.5	No	103

Solvent-refined residual oil (64742-01-4)

OECD 301B	4, 2	No	No Ref
OECD 301B	5, 5	No	44
CEC L-33-T-82	45	Yes	51
CEC L-33-T-82	13	No	53

Distillates, hydrotreated or solvent refined light naphthenic (64742-53-6)

OECD 301F	42	Yes	80

Distillates, hydrotreated heavy paraffinic (64742-54-7)

OECD 301F	31	Yes	83

Distillates, solvent dewaxed light paraffinic (64742-56-9)

OECD 301F	50	Yes	82

Distillate, solvent-dewaxed heavy paraffinic (64742-65-0)

84\449\EEC, C5	23	Yes	102
OECD 301F	38	Yes	81

* Methods used are:

OECD 301B	Ready, Sturm test
OECD 301F	Ready, Manometric method
CEC L-33-T-82	CEC Test
84\449\EEC, C5	Ready, Sturm Test

** For method OECD 301B the two values given for biodegradation are for test material concentrations of 10 and 20 ppm.

(25) (26) (27) (28) (29) (30) (31) (32) (33) (44) (49) (50) (51) (52) (53) (54) (55) (56) (57) (58) (59) (80) (81) (82) (83) (102) (103)

4.1 ACUTE/PROLONGED TOXICITY TO FISH

Type	:	Semi static
Species	:	Salmo gairdneri (Fish, estuary, fresh water)
Exposure period	:	96 hour(s)
Unit	:	mg/l
Limit test	:	Yes
Analytical monitoring	:	Yes
Method	:	OECD Guide-line 203 "Fish, Acute Toxicity Test"
Year	:	1990
GLP	:	Yes
Test substance	:	CAS No. 64741-89-5; distillates (petroleum), solvent-refined, light paraffinic
Result	:	No mortality at 96 hours in the 0 and 1000 mg/l groups. 96 hrs-LL_0 = 1000 mg/l, based on nominal loading rates. Only one concentration was tested in the limit test. The report states that water samples were taken at 0, 24, and 96 hours for analytical verification of test concentrations, but results of any analyses were not reported.
Test condition	:	Daily renewal of the test media ensured that test material levels were maintained at the exposure concentrations. The test media was introduced into the exposure vessels through direct dispersion in water. Shielded propeller-stirrers were utilized to aid in the dispersion of the test material. Observations indicated that the test material was well dispersed throughout the experiment. 20 ml water samples were drawn from the exposure vessels via a glass syringe and delivered to a storage vessel. The syringe was then rinsed with 20 ml of 1,1,2-trichlorotrifluoroethane. Subsequently, the rinse was mixed with the sample prior to storage. Water samples were collected at 0, 24, and 96 hours into the experiment. Samples were stored at 4°C in glass containers until BP International Limited analyzed them. Exposure vessels were glass aquaria equipped with shielded propeller-stirrers containing 20 liters of test media. The stirrers rotated at 2000 rpm. 10 fish were housed in each vessel and 20 fish were exposed at the experimental concentration. The experimental groups included a control and a group exposed to a concentration of 1000 mg/l. The exposure was conducted under a 16 hour/8 hour, light/dark photoperiod. The rainbow trout were supplied by Trafalgar Nurseries, Downton, Salisbury, U.K. The mean length and mean weight (sd) of the experimental fish were 4.8 cm (0.4 cm) and 1.33 g (0.49 g), respectively. Fish were fed commercial trout pellets on a daily basis. Feeding was discontinued 24 hours prior to the initial exposure. The fish were laboratory acclimated for 4 days prior to a one week test condition acclimation. Biomass loading in the test chambers was 0.67 g/l. Test water was tap water, dechlorinated through the addition of sodium thiosulfate. Exposures occurred at 14°C, a hardness of 50 mg/l as $CaCO_3$ and the D.O. level never

dropped below 10.0 mgO_2/l. The pH of the control groups ranged from 7.6-7.7.

Reliability : (2) Valid with restrictions
Only one concentration of the test substance was tested. Results of chemical analyses of test substance concentrations were not reported.

(42)

Method : Acute toxicity tests
Test substance : Various base oils

Remark : Acute fish toxicity studies have been reported for 14 base oil samples (including the study summarized in full above). The results for all 14 samples are summarized in the table below.

Result	Reference
Salmo gairdneri - semistatic test	
Distillates, solvent-refined heavy paraffinic (64741-88-4)	
7-d LL_0=1000 ppm dispersion	48
7-d LL_0=1000 ppm dispersion	40
7-d LL_0=1000 ppm dispersion	38
7-d LL_0=1000 ppm dispersion	39
7-d LL_0=1000 ppm dispersion	46
7-d LL_0=1000 ppm dispersion	60
Distillates, solvent refined light paraffinic (64741-89-5)	
96-h LL_0=1000 ppm dispersion	42
7-d LL_0=1000 ppm dispersion	45
Solvent deasphalted bright stock (64741-95-3)	
96-h LL_0=1000 ppm dispersion	47
Solvent refined residual oil (64742-01-4)	
7-d LL_0=1000 ppm dispersion	43
96-h LL_0=1000 ppm dispersion	41
Pimephales promelas - static test	
Distillates hydrotreated heavy paraffinic (64742-54-7)	
96-h LL_0=100 ppm WAF	78
Solvent dewaxed residual oil (64742-62-7)	
96-h LL_0=100 ppm WAF	79
Distillates solvent dewaxed heavy paraffinic (64742-65-0)	
96-h LL_0=100 ppm WAF	77

(38) (39) (40) (41) (42) (43) (45) (46) (47) (48) (60) (77) (78) (79)

4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

Type : Static
Species : Daphnia magna (Crustacea)
Exposure period : 48 hour(s)
Unit : mg/l

Analytical monitoring	:	No
Year	:	1988
GLP	:	No
Test substance	:	CAS No. 64742-53-6 or 64741-97-5, Distillates (petroleum), hydrotreated or solvent-refined light naphthenic
Result	:	After 48 hrs no daphnid immobilization was found in any of the concentrations tested. The 48 hr EL_0 was 10 g/l. Control survival was 100% after 48 hrs.
Test condition	:	Individual treatment concentrations were prepared as water accommodated fractions (WAF). Nominal loading rates in the definitive test were 0, 0.01, 0.1, 1, and 10 g/l. Control and dilution water was reconstituted hard water prepared by adding salts to glass-distilled deionized water following EPA guidelines (hardness 174 mg/ml as $CaCO_3$). Test substance was mixed in dilution water for 23 hrs. The mixtures were allowed to stand for 1 hr prior to siphoning off the aqueous phase for testing. Glass flasks (140 ml) were filled with each of the WAFs with 10 daphnids per vessel. The flasks were sealed with glass cover slip to minimize the loss of volatile components of the oil. Test daphnids were <24 hrs old and collected from cultures supplied by the testing laboratory that have been aged between 15 and 35 days. Two replicates per treatment and control were used. Black caps were placed over those flasks in which an oily film was visible on the surface of the test solution so the organisms would avoid the darkened zone and not be trapped in the film. Test temperature was 18 - 22 °C. Dissolved oxygen in the control and highest concentration was 8.8 to 9.1 mg/ml. pH in the control and highest concentration was 7.7 - 8.0.
Reliability	:	(2) Valid with restrictions Although test guidelines were not specified and the study was not conducted under GLPs, it was a well-documented study. Analytical monitoring of the oil concentration in the WAFs was not performed. An oily film was visible on the surface of some test solutions apparently as a carryover from the WAF preparations.

(104)

Type	:	Semi static
Species	:	Gammarus pulex (Crustacea)
Exposure period	:	96 hour(s)
Unit	:	mg/l
Analytical monitoring	:	No
Year	:	1988
GLP	:	No
Test substance	:	CAS No. 64742-53-6 or 64741-97-5, Distillates (petroleum), hydrotreated or solvent-refined light naphthenic
Result	:	No dead organisms were found in any of the test vessels after 96 hours. However, some organisms disappeared from all treatments and control throughout the test. It was assumed that these organisms were eaten by the remaining organisms. The numbers of missing animals after 96 hours were 2, 1, 4,

5, and 2 in the control, 0.01, 0.1, 1, and 10 g/l WAFs. Since <50% of the organisms were missing in any concentration, and even if these lost animals died as a result of treatment, the 96-hr LL_0 was 10 g/l.

Test condition : Individual treatment concentrations were prepared as water accommodated fractions (WAF). Nominal loading rates in the definitive test were 0, 0.01, 0.1, 1, and 10 g/l. Control and dilution water was laboratory mains tap water obtained from bore holes, and passed through particle and activated carbon filters (alkalinity 247 mg/ml as $CaCO_3$, hardness 274 mg/ml as $CaCO_3$, conductivity 492 mS/cm, pH 7.3). Test substance was mixed in dilution water for 23 hrs. The mixtures were allowed to stand for 1 hr prior to siphoning off the aqueous phase for testing. Fresh WAFs were prepared for each 24-hr renewal. Glass crystallizing dishes (350 ml) were filled with 300 ml of each of the WAFs with 10 organisms per dish. Three replicates per treatment and control were used. Test organisms were between 1 and 2 mm in size and collected from a tributary of the River Len at Hollingbourne, Kent, UK. Test temperature was 14 - 18.2 °C. Dissolved oxygen in the control and highest concentration was 7.8 to 9.9 mg/ml. pH in the control and highest concentration was 6.8 - 8.5.

Reliability : (2) Valid with restrictions
Although test guidelines were not specified and the study was not conducted under GLPs, it was a well-documented study. Analytical monitoring of the oil concentration in the WAFs was not performed.

(104)

4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE

Species : Scenedesmus subspicatus (Algae)
Endpoint : Growth rate
Exposure period : 96 hour(s)
Unit : mg/l
Limit test : Yes
Analytical monitoring : Yes
Method : OECD Guide-line 201 "Algae, Growth Inhibition Test"
Year : 1991
GLP : Yes
Test substance : CAS No. 64741-88-4; distillates (petroleum), solvent-refined, heavy paraffinic

Remark : Three other base oil samples have been tested for algal toxicity.
The results for all three samples were similar to that described above.
Samples tested at one concentration only were as follows:

CAS No.	Result	Ref.
64741-88-4	96-h LL_0 = 50% WAF	34
64741-89-5	96-h LL_0 = 50% WAF	35
64742-01-4	96-h LL_0 = 50% WAF	37

Result : No inhibition of growth or growth rate were measured at the single test concentration of 50% WAF.

Since there were no observed effects during the study, the 96-hour "No Observed Effect Concentration" (NOEC) was 50% WAF.
The OECD guideline criterion for cell growth in the control group was met in this experiment.

Test condition : Preparation of the Water Accommodated Fraction (WAF): 2.0 grams of test material were placed on 2 Liters of culture medium and stirred via magnetic stirrer for a period of 24 hours prior to the test. Culture medium was prepared according to the guideline formula. After the 24 hour period, stirring was ceased for one hour prior to removing the aqueous phase. The aqueous phase, representing 100% WAF, was then combined with an equal volume of algal suspension. The algal suspension consisted of Scenedesmus cells taken from a culture in logarithmic growth phase and diluted with growth medium to a cell density of 3.70×10^4 cells/ml. The algal species Scenedesmus subspicatus utilized in this study was supplied by the Culture Centre of Algae and Protozoa (CCAP) c/o Institute of Freshwater Ecology, Cumbria, U.K. Sterile culture medium was inoculated with Scenedesmus and incubated under continuous illumination and aeration at 21°C.
10 ml samples of the 50% WAF were taken at times 0 and 96 hours. After adding 10 ml of 1,1,2-trichlorotrifluoroethane, the samples were stored at 4°C until analyzed. Analytical results were not reported.
500 ml of the algal suspension were added to 500 ml of 100% WAF to make the test solution. 100 ml of the test solution was contained in a loosely stoppered 250 ml conical flask. All flasks were incubated and shaken at approximately 100 rpm in an orbital shaker. 6 replicates of a single test concentration and 3 replicates of a control were examined in this study. The flasks were housed under a 24 hour light photoperiod at an intensity of approximately 7,000 lux and a constant temperature of 24°C. No aeration was supplied during the study, however, gas exchange and algal cell suspension was maintained by the orbital shaker. Samples were taken for the determination of algal growth every 24 hours beginning at hour 0 and ending at hour 96.
Absorbances were measured at 665 nm with a Jenway 610 Spectrophotometer. At the initiation and completion of the experiment, the cell densities of the control cultures were determined through direct counting aided by a hemacytometer. The pH of all control and test flasks was taken at 0 and 96 hours. The pH at the beginning and end of the experiment in all groups ranged from 8.3 to 8.5 and 9.4 to 9.9, respectively. The area under the curve and growth rate were taken as indices of algal growth and were calculated using the absorbance readings. Percent inhibition values were calculated for area under the curve and growth rate.

Reliability : (2) Valid with restrictions
Only one concentration of the test substance was tested.
Results of chemical analyses of test substance concentrations were not reported.

(34) (35) (36) (37)

4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

Species	:	Daphnia magna (Crustacea)
Endpoint	:	
Exposure period	:	21 day(s)
Unit	:	mg/l
Analytical monitoring	:	Yes
Method	:	OECD Guide-line 202, part 2 "Daphnia sp., Reproduction Test"
Year	:	1995
GLP	:	Yes
Test substance	:	CAS No. 64741-88-4; distillates (petroleum), solvent-refined, heavy paraffinic
Result	:	After 14 and 21 days of exposure, there were no statistically significant differences between the control group and the 10 and 1000 mg/ml WAF test groups in terms of survival or reproduction (young produced per adult). In addition, there were no apparent effects on the F1 generation produced during the test. The numbers of unhatched eggs and dead young were low in all treatment groups. The NOEC for survival and reproduction was the maximum test concentration, 1000 mg/ml WAF. The test met the validation criteria for 1) dissolved oxygen at least 60%, 2) pH deviation not greater than 0.3, 3) control mortality not greater than 20%, 4) first young (control group) within 9 days, 5) cumulative young per female (control group) at least 20 after 14 days and at least 40 after 21 days, and 6) number of broods per control group at least 3.
Test condition	:	Preparation of the WAF: 20 and 2000 mg of test material were each separately placed in 2 liters of reconstituted water (water hardness approximately 270 mg/ml as $CaCO_2$) and stirred via magnetic stirrer for a period of 24 hours prior to the test. After the 24-hour period, stirring was ceased for one hour prior to removing the aqueous phase. Test Organism Culture: Adult Daphnia magna were maintained in polypropylene vessels containing approximately 2 liters of reconstituted water at a temperature of 21°C. The organisms were supplied by the Institut National de Recherche Appliquée (IRCHA) France. The lighting was held at 16:8 hour light:dark photoperiods. Gravid adults were isolated 24 hours prior to the initiation of the test, the young daphnids produced overnight were removed and utilized for testing. Test Procedure: The aqueous phase of each WAF was removed and 400-ml aliquots were apportioned to five, 500-ml glass flasks. A similar number of control flasks containing reconstituted water also were prepared. The fifth flask from each group was taken for Total Organic Carbon analysis of the exposure

media. At the start of the test, 10 daphnids were placed within each test flask, and all flasks were covered to reduce evaporation. Each vessel received approximately 3.75 x 10^9 cells/ml of a mixed unicellular algae culture as a daily feeding. Fresh WAFs were prepared on days 0, 2, 4, 7, 9, 11, 14, 16, and 18, and the adult daphnids were transferred from the old to the fresh solutions. The numbers of live and dead Daphnia of the parental generation were counted daily. At each test media renewal, Daphnia with eggs or young in the brood pouch, discarded unhatched eggs, and the number of live and dead filial Daphnia were counted.

Temperature was recorded daily for the duration of the experiment, while dissolved oxygen and pH were recorded prior to and after each media renewal. Measurements of TOC were made in the fresh and old test solutions 3 times a week over 21 days. Dissolved oxygen in the control, 10, and 1000 mg/ml WAF groups ranged from 7.9 to 8.3, from 7.9 to 8.3, and from 7.8 to 8.3, respectively. Water pH in the control, 10, and 1000 mg/ml WAF groups ranged from 7.7 to 7.8, from 7.7 to 7.8, and from 7.7 to 7.8, respectively. The temperature within all test groups remained constant at 21.0 °C. The results of the TOC analysis did not demonstrate a direct relationship with WAF concentration, and in many cases the TOC of the control water was higher than that of the test groups. The TOC in the old media tended to be higher than fresh solutions.

Reliability : (2) Valid with restrictions
The analytical results provided no definitive evidence of stability of the test preparations. Only two test concentrations were run.

(62)

Species : Daphnia magna (Crustacea)
Exposure period : 21 day(s)
Unit : mg/l

Remark : In addition to the study described above studies have been reported for ten further base oil samples in 21 day studies with D. magna. In each case OECD guideline 202 part 2 was used as the method.
The results are summarized below:

CAS No.	Result	Reference
64741-88-4	21-d LL_0 = 1000 mg/l WAF	63
64741-88-4	21-d LL_0 = 1000 mg/l WAF	64
64741-88-4	21-d LL_0 = 1000 mg/l WAF	100
64741-89-5	21-d LL_0 = 1000 mg/l WAF	67
64741-89-5	21-d LL_0 = 1000 mg/l WAF	61
64741-95-3	21-d LL_0 = 1000 mg/l WAF	66
64742-01-4	21-d LL_0 = 1000 mg/l WAF	65
64742-53-6	21-d LL_0 = 10 mg/l WAF	101
64742-55-8	21-d LL_0 = 1000 mg/l WAF	100
64742-65-0	21-d LL_0 = 1000 mg/l WAF	100

Of the reported chronic toxicity studies, no chronic effects

were observed below 1 mg/l. For all but two studies, no chronic toxicity was seen at the highest addition of the various base oils tested, which ranged from 1000 to 5000 mg/l.

(61) (63) (64) (65) (66) (67) (100) (101)

5.1.1 ACUTE ORAL TOXICITY

Type	:	LD_{50}
Value	:	> 5000 mg/kg bw
Species	:	Rat
Strain	:	Sprague-Dawley
Sex	:	Male/female
Number of animals	:	5
Vehicle	:	None - administered undiluted
Year	:	1986
GLP	:	Yes
Test substance	:	Unrefined base oil, Sample API 84-01 [CAS 64741-50-0] See section 1.1.1.
Method	:	A single dose of undiluted test material (5g/kg) was administered orally to 5 male and 5 female fasted rats. Food and water was made available ad-lib immediately after dosing. The animals were observed for clinical signs and mortality at hourly intervals for the first 6 hours post dosing and twice daily thereafter. Body weights were recorded prior to fasting, prior to dosing and at 7 and 14 days post dosing. At 14 days, all surviving animals were killed and subjected to a gross necropsy examination.
Result	:	There were no deaths during the study and growth rates were unaffected by dosing. Clinical signs that occurred during the first 3 days included: hypoactivity, diarrhea and a yellow-stained anal area. All animals returned to normal by day 14. At gross necropsy, there were no visible lesions.
Reliability	:	(1) Valid without restriction

(12)

Type	:	LD_{50}
Value	:	> 5000 mg/kg bw
Species	:	Rat
Strain	:	Sprague-Dawley
Sex	:	Male/female
Number of animals	:	5
Vehicle	:	Non - administered undiluted
Year	:	1986
GLP	:	Yes
Test substance	:	Highly refined Base oil Sample API 83-12 [CAS64742-53-6] See section 1.1.1.
Method	:	A single dose of undiluted test material (5g/kg) was administered orally to 5 male and 5 female fasted rats. Food and water was made available ad-lib immediately after dosing. The animals were observed for clinical signs and mortality at hourly intervals for the first 6 hours post dosing and twice daily thereafter. Body weights were recorded prior to fasting, prior to dosing and at 7 and 14 days post dosing. At 14 days, all surviving animals were killed and subjected to a gross necropsy examination.
Result	:	There were no deaths during the study. Clinical signs observed included: hypoactivity,

yellow-stained anal area, hair loss in the urogenital region and swollen hind paws.
All animals returned to normal by day 3 and had gained weight by day 7.
At necropsy, there were no visible lesions except in one female in which the spleen was cystic, mottled red and tan and had a rough surface. In this animal the pancreas adhered to the entire surface of the spleen.

Reliability : (1) Valid without restriction

(11)

Type : LD_{50}
Species : Rat
Test substance : Various Base oils

Remark : CONCAWE summarized the data available on the acute oral toxicity of lubricating oil base stocks. The data are shown in the following table.

	CAS No.	Oral LD_{50} (g/kg)	API Report No
Paraffinic distillates			
Solvent dewaxed, light			
API 78-9	64742-56-9	>5	29-33104
Solvent dewaxed, heavy			
API 78-10*	64742-56-0	>5	29-33105
API 79-3	64742-65-0	>5	29-33067
API 79-4	64742-65-0	>5	29-33066
API 79-5	64742-65-0	>5	29-33068
White mineral oil			
Tufflo 6056*		>5	39-31651
Naphthenic distillates			
Solvent refined, light			
API 78-5	64741-97-5	>5	29-33106
Solvent refined, heavy			
API 79-1	64741-96-4	>5	29-33065
Hydrotreated, heavy			
API 83-15	64742-52-5	>5	33-32639

* Although this material is not included in the HPV Lubricating base stocks category, it is similar to other materials in the category and provides supportive information.

(2) (3) (4) (5) (6) (7) (8) (13) (71)

5.1.2 ACUTE INHALATION TOXICITY

Type : LC_{50}
Value : 2.18 mg/l

Species	:	Rat
Strain	:	Sprague-Dawley
Sex	:	Male/female
Number of animals	:	5
Vehicle	:	Air
Exposure time	:	4 hour(s)
Year	:	1987
GLP	:	Yes
Test substance	:	Highly refined Base oil Sample API 83-12 [CAS64742-53-6] See section 1.1.1.

Method : A group of 5 male and 5 female rats were exposed for 4 hours to an aerosol of the test material at a target concentration of 5 mg/l. Four additional groups of rats were then exposed for 4 hours to target aerosol concentrations of 1, 1.5, 2.5 and 3.5 mg/l. A control group exposed, in the chamber, to air only was also included.
Animals were observed continuously during the first hour of exposure, hourly for the remainder of the exposure and once daily for the 14-day post exposure period. Mortalities were recorded and body weights were measured prior to exposure and again 7 and 14 days after exposure. On the 14th day post-exposure, necropsies were performed on all surviving animals. For all animals, including animals found dead, the lungs and any other abnormal tissues were removed and fixed for subsequent histopathological examination.

Result : Actual exposure concentrations and mortalities were as follows:

Target level (mg/l)	Actual concentration mg/l	±SD	Mortality Male	Female
0	0.02	0.01	0/5	0/5
1.0	1.04	0.1	1/5	1/5
1.5	1.51	0.15	0/5	0/5
2.5	2.37	0.31	3/5	3/5
3.5	3.49	0.36	5/5	5/5
5.0	5.05	0.18	5/5	5/5

Particle size measurements confirmed that mass median aerodynamic diameter and geometric standard deviation values were in the ranges 1.7 to 2.5 mμ and 1.5 to 1.61 respectively. These measurements confirm that the particles were within the respirable range.
The LC_{50} for combined sexes was estimated to be 2.18 with 95% confidence limits of 1.80 to 2.55 mg/l.

Body weight differences did not show a consistent dose related pattern.

At the highest concentration, the animals were obscured by a dense aerosol and observations could not be made during the exposure period. In other groups, there was a decreased activity, wet inguinal area, eyes partially closed, wet coat, loose stool and oily coat during exposure.
During the first week post-exposure, similar signs were observed as well as signs of poor condition, respiratory distress and some deaths occurred. During test week 2, most

survivors were considered to be of normal appearance. The signs that were observed occurred in a dose related manner.

At gross necropsy, dark red lungs were described for some animals. The incidence is shown below.

Dose group	Male	Female
0	0/5	0/5
1.0	1/5	1/5
1.5	0/5	0/5
2.5	3/5	3/5
3.5	5/5	5/5
5.0	5/5	5/5

At histology, affected animals exhibited diffuse pulmonary congestion and perivascular edema that were mostly moderate or marked in degree. Less consistently spotty alveolar edema was also seen. There was widespread damage to alveolar walls resulting in fibronecrotic debris resembling hyaline membranes in more marked cases and extravasation of RBCs and PMNs. Necrosis and inflammation were seen in the walls of small blood vessels and there was spotty epithelial necrosis in small bronchioles, but the most severe damage seemed to be centroacinar. The larger airways were relatively unaffected.

None of the surviving animals exhibited the above acute changes. However, most of the surviving animals exposed to 2.5 or 1.0 mg/l and above exhibited chronic inflammatory changes that were not seen in the controls and only occasionally in animals exposed at the 1.5 mg/l level, and then to a lesser degree of severity.
Other findings were considered sporadic or unrelated to exposure to the test material.

Test condition : Whole body exposures were carried out in stainless steel and glass chambers of 0.25 cubic meter volume.
Aerosols were generated using a nebulizer.
Concentrations of test material in the exposure chambers were determined gravimetrically by collection of the aerosol on filters. Analytical samples were taken at least once per hour during the exposure period. Particle size determinations were also carried out.

Reliability : (1) Valid without restriction

(15)

Type : LC_{50}
Species : Rat
Test substance : Various Base oils

Remark : CONCAWE summarized the data available on the acute inhalation toxicity of lubricating oil mists in 4 hour exposure studies in rats.
The data (Original source Whitman et al, 1989) on 3 paraffinic distillates are shown in the following table.

Inhalation LC_{50}

	(mg/l)
Paraffinic distillates	
Solvent extracted, dewaxed	>4
Solvent extracted, dewaxed, hydrotreated	>4
Solvent dewaxed, light	>4

(71) (111)

5.1.3 ACUTE DERMAL TOXICITY

Type : LD_{50}
Value : > 2000 mg/kg bw
Species : Rabbit
Strain : New Zealand white
Sex : Male/female
Number of animals : 4
Vehicle : None applied undiluted
Year : 1986
GLP : Yes
Test substance : Unrefined base oil Sample API 84-01 [CAS 64741-50-0] See section 1.1.1.

Method : Undiluted test material was applied as a single dose (2g/kg) to the shorn, abraded skin of 4 male and 4 female rabbits. The treated site was covered with an occlusive dressing for 24 hours. After removal of the dressing, the skin was wiped with a wet towel to remove residual test material. The rabbits were observed for clinical signs and mortality hourly for the first 6 hours, then daily for dermal irritation and twice daily for clinical signs and mortality. Observation was carried out for a 14-day post treatment period. Body weights were recorded prior to administration of the test material, again 7 days post dosing and at study termination (14 days). At termination, all surviving animals were killed and subjected to a gross necropsy examination.

Result : There were no mortalities during the study.
With the exception of skin irritation, there were no clinical signs of toxicity except that on day 4 soft stool was observed in 1 male and 3 female animals.
Dermal irritation ranged from slight to severe for erythema and edema, from slight to marked for fissuring and slight to moderate for atonia and desquamation. Slight coriaceousness was also observed.
Body weight losses were recorded for 2 male and 3 female animals at day 7. One male was less than starting weight on both day 7 and day 14.

Reliability : (1) Valid without restriction

(12)

Type : LD_{50}
Value : > 2000 mg/kg bw
Species : Rabbit
Strain : New Zealand white
Sex : Male/female
Number of animals : 2
Vehicle : None - applied undiluted
Year : 1986
GLP : Yes

Test substance : Highly refined Base oil Sample API 83-12 [CAS64742-53-6] See section 1.1.1.

Method : Undiluted test material was applied as a single dose (2g/kg) to the shorn, abraded skin of 4 male and 4 female rabbits. The treated site was covered with an occlusive dressing for 24 hours. After dressing removal, the skin was wiped with a wet towel to remove residual test material. The rabbits were observed for clinical signs and mortality hourly for the first 6 hours, then daily for dermal irritation and twice daily for clinical signs and mortality. Observation was carried out for a 14-day post treatment period. Body weights were recorded prior to administration of the test material, again 7 days post dosing and at study termination (14 days). At termination, all surviving animals were killed and subjected to a gross necropsy examination.

Result : There were no deaths during the study.
The only clinical observation with the exception of skin irritation was soft stool in all animals. This was observed 3 hours after dosing and returned to normal by day 2.
Skin irritation was observed in all animals and ranged from slight to severe for erythema and edema, from slight to marked for atonia, desquamation and fissuring and from slight to moderate for coriaceousness. Other dermal irritation seen included blanching and subcutaneous hemorrhage.
All animals had gained weight by the end of the study.
At necropsy, except for the skin lesions no other visible lesions were recorded.

Reliability : (1) Valid without restriction

(11)

Type : LD_{50}
Species : Rabbit
Test substance : Various Base oils

Remark : CONCAWE summarized the data available on the acute dermal toxicity of lubricating oil base stocks in rabbits. The data are shown in the following table.

	CAS No	Dermal LD_{50} (g/kg)	API Report No.
Paraffinic distillates .			
Solvent dewaxed, light			
API 78-9	64742-56-9	>5	29-33104
Solvent dewaxed, heavy			
API 78-10*	64742-56-0	>5	29-33105
API 79-3	64742-65-0	>5	29-33067
API 79-4	64742-65-0	>5	29-33066
API 79-5	64742-65-0	>5	29-33068
Naphthenic distillates			
Solvent refined, light			
API 78-5	64741-97-5	>5	29-33106

Solvent refined, heavy			
API 79-1	64741-96-4	>5	29-33065
Hydrotreated, heavy			
API 83-15	64742-52-5	>2	33-32639

* Although this material is not included in the HPV Lubricating base stocks category, it is similar to other materials in the category and provides supportive information

(2) (3) (4) (5) (6) (7) (8) (13) (71)

5.2.1 SKIN IRRITATION

Species : Rabbit
Concentration : Undiluted
Exposure : Occlusive
Exposure time : 24 hour(s)
Number of animals : 6
Vehicle : None - undiluted
PDII : 4.3
Result : Moderately irritating
Method : Draize Test
Year : 1986
GLP : Yes
Test substance : Unrefined base oil, Sample API 84-01 [CAS 64741-50-0] See section 1.1.1.

Method : 0.5 ml of undiluted test material was applied to the shorn dorsal skin in two areas on each of 6 male rabbits. One area was intact and the other abraded skin. The treated area was then covered with an occlusive dressing.
After 24 hours, the dressing was removed and the treated skin
was wiped to remove any residue of test material. The degree of erythema and edema was recorded according to the Draize scale. A second reading of skin responses was made at 72 hours and again at 96 hours, 7 and 14 days. Results of the 24 and 72-hour readings were used to determine the Primary Irritation Index.

Result : One animal died on day 10 even though there had been no signs of ill health previously. Irritation scores given below are averages from 5 animals.

Observation period	Erythema Intact	Erythema Abraded	Edema Intact	Edema Abraded	Average Score
24 hrs.	2.3	2.5	2.3	2.3	4.8
72 hrs.	1.8	2.0	1.7	2.0	3.8
96 hrs.	1.5	1.7	1.0	1.0	2.6
7 days	0.3	0.3	0.3	0.5	0.8
14 days	0	0	0	0	0

Primary dermal irritation index: 4.3

Reliability : (1) Valid without restriction

(12)

Species : Rabbit
Concentration : Undiluted

Exposure : Occlusive
Exposure time : 24 hour(s)
Number of animals : 6
Vehicle : None - undiluted
PDII : 5.4
Result : Moderately irritating
Method : Draize Test
Year : 1986
GLP : Yes
Test substance : Highly refined Base oil, Sample API 83-12 [CAS64742-53-6] See section 1.1.1.

Method : 0.5 ml of undiluted test material was applied to the shorn skin in two areas on each of 6 male rabbits. One area was intact and the other abraded skin. The treated area was then covered with an occlusive dressing.
After 24 hours, the dressing was removed and the treated skin
was wiped to remove any residue of test material. The degree of erythema and edema was recorded according to the Draize scale. A second reading of skin responses was made at 72 hours and again at 96 hours, 7 and 14 days. Results of the 24 and 72-hour readings were used to determine the Primary Irritation Index.

Result : Average Irritation scores are given below:

Observation period	Erythema Intact	Erythema Abraded	Edema Intact	Edema Abraded	Average Score
24 hrs.	2.3	2.3	2.7	2.7	5.0
72 hrs.	3.0	3.0	2.5	3.0	5.8
96 hrs.	2.7	2.8	2.7	3.0	5.6
7 days	1.3	2.2	0.8	1.7	3.0
14 days	0	0	0	0	0

Primary dermal irritation index: 5.4

Reliability : (1) Valid without restriction

(11)

Species : Rabbit
Concentration : Undiluted
Exposure time : 24 hour(s)
Test substance : Various base oils

Remark : CONCAWE summarized the data available on skin irritation for the lubricating oil base stocks. The data are shown in the following table.

	Irritation*	API Report
Paraffinic distillates		
Solvent dewaxed, light API 78-9 (64742-56-9)	Slight (0.6)	29-33104
Solvent dewaxed, heavy		

API 78-10*** (64742-56-0)	Non (0.27)	29-33105
API 79-3 (64742-65-0)	Non (0.33)	29-33067
API 79-4 (64742-65-0)	Non (0.34)	29-33066
API 79-5 (64742-65-0)	Non (0.38)	29-33068
White mineral oil* **	Slight	Hoekstra & Phillips
Naphthenic distillates		
Solvent refined, light		
API 78-5 (64741-97-5)	Slight (0.65)	29-33106
Solvent refined, heavy		
API 79-1 (64741-96-4)	Slight (0.8)	29-33065
Hydrotreated, heavy		
API 83-15 (64742-52-5)	Slight (1.3)**	33-32639

* Irritation described as slight, moderate or non-irritating in the original reports (Mean irritation score given in parentheses)

** Irritation index

*** Although this material is not included in the HPV Lubricating base stocks category, it is similar to other materials in the category and provides supportive information

(2) (3) (4) (5) (6) (7) (8) (13) (71)

5.2.2 EYE IRRITATION

Species	:	Rabbit
Concentration	:	Undiluted
Dose	:	.1 ml
Number of animals	:	9
Method	:	Draize Test
Year	:	1986
GLP	:	Yes
Test substance	:	Unrefined base oil, Sample API 84-01 [CAS 64741-50-0] See section 1.1.1.
Method	:	0.1 ml of undiluted test material was applied to the corneal surface of one eye of each of 9 rabbits, the other eye was untreated and served as control. After 20 to 30 seconds, the treated eyes of 3 rabbits were washed with lukewarm water for 1 minute. Eyes of the other 6 rabbits were not washed. Readings of ocular lesions for all animals were made at 1, 24, 48, 72 hours and 7 days after treatment. Sodium fluorescein was used to aid in revealing possible corneal injury.
Result	:	One animal died on day 7 but this was not considered to be treatment related. The test material did not cause a pain response, corneal or iridial irritation. The eye irritation that occurred had cleared by 48 hours. The primary eye irritation scores (according to the standard Draize scoring procedure) were as follows:

Period	Unwashed eyes	Washed eyes
1 hour	3.0	4.0
24 hours	1.7	0

Scores of 0 were recorded at all other observation times.

Reliability : (1) Valid without restriction

(12)

Species : Rabbit
Concentration : Undiluted
Dose : .1 ml
Number of animals : 9
Method : Draize Test
Year : 1986
GLP : Yes
Test substance : Highly refined Base oil, Sample API 83-12 [CAS64742-53-6] See section 1.1.1.

Method : 0.1 ml of undiluted test material was applied to the corneal surface of one eye of each of 9 rabbits, the other eye was untreated and served as control.
After 20 to 30 seconds, the treated eyes of 3 rabbits were washed with lukewarm water for 1 minute. Eyes of the other 6 rabbits were not washed.
Readings of ocular lesions for all animals were made at 1, 24, 48, 72 hours and 7 days after treatment. Sodium fluorescein was used to aid in revealing possible corneal injury.

Result : There was no pain response during instillation of the test material and no corneal or iridial irritation was seen during the study.
Any irritation that occurred had cleared by 48 hours.
The primary eye irritation scores for the first 48 hours of the study were as follows:

Period	Unwashed eyes	Washed eyes
1 hour	2.7	2.0
24 hours	0.3	0
48 hours	0	0

Reliability : (1) Valid without restriction

(11)

Species : Rabbit
Concentration : Undiluted
Dose : .1 ml
GLP :
Test substance : Various base oils

Remark : CONCAWE summarized the data available on eye irritation for the lubricating oil base stocks. The data are shown in the following table.

	Irritation*	API report No.
Paraffinic distillates		
Solvent dewaxed, light		

API 78-9 (64742-56-9)	Slight	29-33104
Solvent dewaxed, heavy		
API 78-10** (64742=56-0)	Non	29-33105
API 79-3 (64742-65-0)	Non	29-33067
API 79-4 (64742-65-0)	Non	29-33066
API 79-5 (64742-65-0)	Non	29-33068

Naphthenic distillates

Solvent refined, light		
API 78-5 (64741-97-5)	Non	29-33106
Solvent refined, heavy		
API 79-1 (64741-96-4)	Non	29-33065
Hydrotreated, heavy		
API 83-15 (64742-52-5)	Slight	33-32639

Other mineral oils

Paraffin oil**	Slight	Carpenter & Smyth

* NB Irritation described as slight, moderate or non-irritating

** Although this material is not included in the HPV Lubricating base stocks category, it is similar to other materials in the category and provides supportive information

(2) (3) (4) (5) (6) (7) (8) (13) (68) (71)

5.3 SENSITIZATION

Type : Buehler Test
Species : Guinea pig
Concentration : 1st: Induction 25 % occlusive epicutaneous
2nd: Challenge 1 % occlusive epicutaneous
Number of animals : 10
Vehicle : Paraffin oil
Result : Not sensitizing
Year : 1986
GLP : Yes
Test substance : Unrefined base oil, Sample API 84-01 [CAS 64741-50-0] See section 1.1.1.

Method : 0.4 ml of a 25% mixture of test material and paraffin oil was applied under an occlusive dressing to the shorn skin of 10 male and 10 female animals. 6 hours after application the dressings were removed and the skin wiped to remove residues of test material. The animals received one application each week for 3 weeks. The same application site was used each time. 2 weeks following the third application, a challenge dose (0.4 ml of a 1% mixture in paraffin oil) was applied in the same manner as the sensitizing doses. A previously untreated site was used for the challenge application. The application sites for sensitizing and challenge doses were read for erythema and edema 24 and 48 hours after patch removal. To assist in the reading of the response to the final challenge dose the test site was depilated 3 hours prior to reading by using a commercially available depilatory cream.

Positive control (2,4-dinitrochlorobenzene at 0.3% in 80% aqueous ethanol), vehicle control and naive control groups were included in this study and the procedure for these was the same as for the test groups.

Result : The criteria used to evaluate the responses are described in the report as follows:
Determination of sensitization was based upon reactions to the challenge dose. Grades of 1 or greater in the test animals indicate evidence of sensitization, provided grades of less than 1 are seen in the naive controls. If grades of 1 or greater are noted in the naive control animals, then the reactions of test animals that exceed the most severe naive control reaction are considered sensitization reactions.

Using these criteria, none of the test animals became sensitized following treatment with API 84-01. In contrast, all the positive control animals were sensitized by their treatment.

Reliability : (1) Valid without restriction

(12)

Type : Buehler Test
Species : Guinea pig
Concentration : 1st: Induction 50 % occlusive epicutaneous
2nd: Challenge 1 % occlusive epicutaneous
3rd:
Number of animals : 10
Vehicle : Paraffin oil
Result : Not sensitizing
Year : 1986
GLP : Yes
Test substance : Highly refined Base oil, Sample API 83-12 [CAS64742-53-6]
See section 1.1.1.

Method : 0.4 ml of a 50% mixture of test material and paraffin oil was applied under an occlusive dressing to the shorn skin of 10 male and 10 female animals. 6 hours after application, the
dressings were removed and the skin wiped to remove residues of test material. The animals received one application each week for 3 weeks. The same application site was used each time. 2 weeks following the third application, a challenge dose (0.4 ml of a 1% mixture in paraffin oil) was applied in the same manner as the sensitizing doses. A previously untreated site was used for the challenge application.
The application sites for sensitizing and challenge doses were read for erythema and edema 24 and 48 hours after patch removal. To assist in the reading of the response to the final challenge dose the test site was depilated 3 hours prior to reading by using a commercially available depilatory cream.

Positive control (2,4-dinitrochlorobenzene at 0.3% in 80% aqueous ethanol), vehicle control and naive control groups were included in this study and the procedure for these was the same as for the test groups.

Result	:	The criteria used to evaluate the responses are described in the report as follows: Determination of sensitization was based upon reactions to the challenge dose. Grades of 1 or greater in the test animals indicate evidence of sensitization, provided grades of less than 1 are seen in the naive controls. If grades of 1 or greater are noted in the naive control animals, then the reactions of test animals that exceed the most severe naive control reaction are considered sensitization reactions. One animal had a score of 0.5 after challenge with API 83-12. In contrast, all the positive control animals were sensitized by their treatment. The sample of API 83-12 was therefore non sensitizing.
Reliability	:	(1) Valid without restriction

(11)

Type : Buehler Test
Species : Guinea pig
Test substance : Various base oils

Remark : CONCAWE summarized the data available on skin sensitization for the lubricating oil basestocks. The methods and criteria used were the same as those described in the previous two robust summaries. The data are shown in the following table.

		Sensitization	API Report
Paraffinic distillates			
Solvent dewaxed, light			
API 78-9	64742-56-9	Non	29-33104
Solvent dewaxed, heavy			
API 78-10*	64742-56-0	Non	29-33105
API 79-3	64742-65-0	Non	29-33067
API 79-4	64742-65-0	Non	29-33066
API 79-5	64742-65-0	Non	29-33068
Naphthenic distillates			
Solvent refined, light			
API 78-5	64741-97-5	Non	29-33106
Solvent refined, heavy			
API 79-1	64741-96-4	Non	29-33065
Hydrotreated, heavy			
API 83-15	64742-52-5	Non	33-32639

* Although this material is not included in the HPV Lubricating base stocks category, it is similar to other materials in the category and provides supportive information

(2) (3) (4) (5) (6) (7) (8) (13) (71)

5.4 REPEATED DOSE TOXICITY

Type	:	Sub-acute
Species	:	Rat
Sex	:	Male/female
Strain	:	No data
Route of admin.	:	Inhalation
Exposure period	:	14 days
Frequency of treatm.	:	Six hours per day
Control group	:	Yes
NOAEL	:	> 50 mg/m³
Year	:	1989
GLP	:	No data
Test substance	:	Two samples of highly refined, solvent extracted dewaxed paraffinic base oil

Method :

Groups of 5 male and 5 female rats were exposed to oil mists generated from two highly refined oils. Exposures were by inhalation six hours each day for a total of 10 days
The two oils were examined in separate experiments.
The dose groups were:

Group	Mean actual concentration (mg/m^3)	Mass median particle size (µm)
Controls	Air only	N/A
Oil 1	55	1.5
	507	1.9
	1507	2.2
Oil 2	Air only	N/A
	50	1.5
	513	1.9
	1480	2.2

No further experimental details are provided.

Remark :

A further two week inhalation study in rats has been reported for two mineral oil mists (Skyberg et al, 1990)
The results largely confirm those described by Whitman et al. with respect to liver weight changes and histological observations in respiratory tissues.

Result :

Oil 1
All treated animals survived to study termination.
The fur of all animals was saturated with test material and the amount of material present was clearly related to the exposure concentration.
Alopecia and scabs subsequently formed in the highest 2 dose groups.
Animals in the highest dose group were relatively unresponsive to auditory stimulation.
Decreased body weight associated with a decrease in food consumption was recorded for the high dose animals.

Biologically significant increases in relative lung and liver weights were observed in he males and females in the

high dose group but only in the mid dose females.
An increase in white cell counts and the percentage of neutrophils and a decrease in the percentage lymphocytes was observed in the high dose groups only.
There were no treatment related histopathological changes in the lowest 2 dose groups. Animals in the highest dose group exhibited the same changes as those observed in the nasoturbinates and lungs of animals exposed to oil 2 (See below)

Oil 2
Clinical observations were the same as for those animals exposed to Oil 1, except that there was no scabbing and no treatment related alterations in food consumption.
There was a biologically significant increase in absolute and relative lung weights in males and females at the high dose and in females only at the mid dose.
Apart from elevated liver alanine and aspartate transaminase levels in the high dose females there were no other treatment related effects.
Histological effects considered to be treatment related consisted of an increase in the amount of perivascular and peribronchial lymphoid proliferations and an increase in mixed inflammatory cell infiltrations in the terminal bronchioles and alveolar ducts of the highest two dose groups. Increases in the appearance of focal hyperplasia and squamous cell metaplasia of the anterior nasal mucosa associated with inflammatory cell infiltration were observed in the two highest dose groups. These changes were indicative of mild irritation of the nasal mucosa.

The NOELs for the two oils were >50 mg/m^3

Reliability : (4) Not assignable
The information is taken from a poster presentation and a reliability score cannot be assigned.
However, the data are supportive of the other study on inhalation of oil mist reported by Dalbey et al.

(106) (111)

Type : Sub-acute
Species : Rat
Sex : Male/female
Strain : Sprague-Dawley
Route of admin. : Inhalation
Exposure period : 4 weeks
Frequency of treatm. : 6 hours/day, 5 days/week
Doses : 50, 220 & 1000 mg/m^3
Control group : Yes, concurrent no treatment
Year : 1991
GLP : No data
Test substance : 3 base oils

Method : Groups of 10 male and 10 female rats were exposed to aerosol concentrations of the three test materials at nominal concentrations of 0, 50, 220 and 1000 mg/m^3.
Exposures were for 6 hours each day, 5 days each week for 4 weeks. Total number of exposures for each of the three test

materials was: 17, 18 and 20 days for SRO, WTO and HBO respectively. Food and water were available ad libitum during non-exposure periods.
Clinical observations were made prior to each exposure and body weights were recorded weekly.
Animals were sacrificed within 72 hours of the last exposure after being fasted overnight. Blood samples wee taken for a range of hematology and serum chemical parameters. The hematological parameters consisted of: Total white and red cells, hemoglobin, hematocrit, MCV, MCH, and MCHC. A differential white cell count was also conducted.
The following chemical parameters were measured: Alanine transferase, albumin, albumin/globulin ratio, alkaline phosphatase, aspartate aminotransferase, total bilirubin, calcium, chloride, cholesterol, creatinine, globulin, glucose, iron, lactate dehydrogenase, inorganic phosphorus, potassium, total protein, sodium, triglycerides, urea nitrogen and uric acid.
All animals were necropsied and the following organs were weighed: gonads, heart, kidneys, liver, spleen, and thymus. The right middle lobe of the lung was weighed immediately after removal and again after drying.
A range of tissues were fixed and prepared for a histopathological examination.
Sperm from the cauda epididymis of each control and high dose male was examined for an assessment of sperm morphology.

Result : Chamber concentrations
The aerosol concentrations were comparable among the three base stocks.
Qualitatively, the aerosols were virtually identical to each liquid base oil.
The actual concentrations for each of the aerosols was as follows:

	Nominal	Actual
SRO	0	0
	50	50 ±10
	220	210 ±10
	1000	1020 ±60
WTO	0	0
	50	50 ±10
	220	210 ±10
	1000	980 ±20
HBO	0	0
	50	47 ±2
	220	220 ±10
	1000	980 ±50

The mass median diameter was well under 2µm for each base stock

Toxicity assessment

Apart from occasional loose stool there were no treatment related clinical observations and body weights were

unaffected by exposure.
No treatment related effects were found in any of the hematological or clinical chemical parameters that were measured.
The percent sperm with aberrant morphology, including breakage, was unaffected by exposure to any of the three base oils.
There were no treatment-related observations at necropsy and, with the exception of the lungs, there were no significant changes in organ weights.
Wet and dry lung weights increased in a dose-related manner. The percentage increases in wet weight are shown in the following table.
For simplicity increases are shown to nearest whole numbers

		% Increase in wet lung weight		
Sex	**Dose**	**SRO**	**WTO**	**HBO**
Female	(mg/m^3)			
	50	3	8	2
	210	4	23*	34*
	1000	38*	64*	36*
Male				
	50	5	-	1
	210	12*	1	6
	1000	33*	31*	32*

* denotes differences that are statistically significant ($P<0.05$) compared to controls.
The ratios of wet to dry lung weights were significantly increased for both sexes at the highest dose concentration for all three base oils.

Morphologically, treatment related changes were only observed in the lungs and tracheobronchial lymph nodes. Foamy macrophages with numerous vacuoles of varying size were present in the alveolar spaces of the lungs of many of the exposed animals. The histological changes are summarized in the following table.

No. of animals in each group with a given histopathological change

Tissue/change	**Dose group**		
	50	**210**	**1000**
SRO			
Lung			
1-2 Foamy macrophages (FM)	20	20	20
3-6 FM	0	0	20
Thickened alveolar wall	0	0	0
FM in alveolar interstitium	0	0	0
Mild alveolar PMN infiltrate	0	5	20
Lymph nodes			
Anterior mediastinal			
Macrophage accumulation	NE	NE	9
Tracheobronchial			

FM accumulation	NE	NE	19
Macrophage accumulation	NE	NE	0
WTO			
Lung			
1-2 Foamy macrophages (FM)	20	20	20
3-6 FM	0	0	20
Thickened alveolar wall	0	0	0
FM in alveolar interstitium	0	0	0
Mild alveolar PMN infiltrate	0	0	19
Lymph nodes			
Anterior mediastinal			
Macrophage accumulation	NE	NE	0
Tracheobronchial			
FM accumulation	NE	NE	0
Macrophage accumulation	NE	NE	19
HBO			
Lung			
1-2 Foamy macrophages (FM)	0	16	16
3-6 FM	0	0	16
Thickened alveolar wall	0	0	16
FM in alveolar interstitium	0	0	16
Mild alveolar PMN infiltrate	0	0	0
Lymph nodes			
Anterior mediastinal			
Macrophage accumulation	NE	NE	2
Tracheobronchial			
FM accumulation	NE	NE	0
Macrophage accumulation	NE	NE	3

NE denotes Not Evaluated
Only 16 animals in the HBO high dose group were examined

Test substance : Three materials were examined in this study. The properties of the materials designated SRO, WTO and HBO are shown in the following table.

SRO Solvent refined oil CAS # 64742-70-7

WTO White oil CAS # 8042-47-5. [Prepared by severely hydrotreating a dewaxed feedstock and then acid washing with fuming sulfuric acid.]

HBO Hydrotreated base oil CAS #64742-54-7 [Severely hydrotreated heavy paraffinic oil produced by treatment of the vacuum distillate with hydrogen at high temperature and pressure (hydrotreating and hydrocracking)].

	SRO	WTO	HBO
Viscosity at 100 °F	106	85	161
Pour point (°F)	20	15	-5
API Gravity	32.8	34.6	33.6
Furfural (ppm)	1	0	<1
Nitrogen (ppm)	44	-	8
Sulfur (wt.%)	0.20	-	<0.06
Composition (wt.%)			

Paraffins	36	60	29.7
Mononaphthenes	22.3	-	30.6
Polynaphthenes	22.3	-	37.3
Monoaromatics	12.8	0	0.6
Diaromatics	3.3	0	0.8
Polyaromatics	1.4	0	1.0
Unidentified aromatics	0.4	0	0
Aromatic sulfur types	1.1	0	0

Reliability : (2) Valid with restrictions
It is not clear whether the study was carried out according to GLP, but otherwise it was a well conducted and well reported study.

(73)

Type :
Species : Rabbit
Sex : Male/female
Strain : New Zealand white
Route of admin. : Dermal
Exposure period : 6 hours each day
Frequency of treatm. : 3 times each week for a total of 12 applications
Doses : 200, 1000 and 2000 mg/kg
Control group : Yes
Year : 1986
GLP : Yes
Test substance : Unrefined base oil Sample API 84-01 [CAS 64741-50-0] See section 1.1.1.

Method : Undiluted API 84-01 was applied at doses of 200, 1000 and 2000 mg/kg/day to the shorn dorsal skin of groups of five male and five female rabbits. The test material was applied to the skin 3 times each week for 4 weeks (12 applications total). The applied material was covered with an occlusive dressing for 6 hours, which was then removed and the skin was
wiped with a dry gauze to remove any residual material. A group of five rabbits of each sex served as sham controls. The test skin site of each animal was examined and scored for irritation prior to each application of test material. Mortality and moribundity checks were performed twice daily and body weights were recorded weekly. At termination, blood samples were taken for a range of hematological and clinical chemical measurements. Urine samples were also collected and frozen for possible future examination. A complete gross necropsy was performed on all animals. Major organs were weighed and tissues were processed for subsequent histopathological examination.

Result : Three animals died during the study but these were not dose-related and were, therefore, considered unrelated to treatment. Sporadic clinical signs were also unrelated to treatment.
In the high dose group, body weight gains were affected by treatment. In the females, there was a group net loss in weight whereas in the males the gains were significantly less than controls. These effects were largely due to effects on growth rate during the first week of the study.
A mean irritation index was calculated for each group each day and also for each treatment group overall. The value

was determined from Draize scores for erythema and edema for each animal. The mean irritation scores for each group were:

Group	Irritation score
Control (male)	0
Control (female)	0
200 mg/kg (male)	0.5
200 mg/kg (female)	0.4
1000 mg/kg (male)	1.7
1000 mg/kg (female)	2.0
2000 mg/kg (male)	3.1
2000 mg/kg (female)	3.2

There were no statistical differences between treated and control groups for any of the hematological determinations. These were: Total red blood cells, total white blood cells, hemoglobin concentration and hematocrit %.

The clinical chemical data for the treated and control males was similar. In the females, there was a reduced BUN and an increased SGPT for the low dose females. Since no other differences were noted and that values were within normal limits the effects were not considered to be toxicologically significant. The clinical chemical measurements consisted of: glucose, BUN, SGOT, SGPT, ALP and total protein.

The following absolute and relative organ weight differences (compared to controls) were recorded.

2000 mg/kg

	Males	Females
Relative liver wt.	Increased	Increased
Relative kidney wt.	Increased	Increased
Relative pituitary wt.	Increased	
Relative left testis wt.	Decreased	
Relative brain wt.		Increased

1000 mg/kg

Abs. Rt. kidney wt.	Decreased
Abs. Heart wt.	Decreased

None of the organ weight differences were considered treatment-related. The higher than control relative organ weights were considered as a function of the reduced body weights in the affected animals.

The only findings at gross necropsy were confined to the treated skin. These consisted of dry, scaly, rough, and/or reddened skin and thickened dermis. These findings were noted throughout the treatment groups. There were no treatment-related gross necropsy findings in the internal organs.

Microscopic pathology findings were also largely confined to the skin. Slight to moderate proliferative changes of the

skin were present in all of the male and female rabbits in the highest dose group.

The testes of one of the five males in the high dose group had bilateral diffuse tubular hypoplasia accompanied by aspermatogenesis and hypoplasia of the epididymis. These changes were considered to represent immature testes. Similar changes were not seen in the other animals in this dose group.

Reliability : (1) Valid without restriction

(10)

Type	:	
Species	:	Rabbit
Sex	:	Male/female
Strain	:	New Zealand white
Route of admin.	:	Dermal
Exposure period	:	6 hours each day
Frequency of treatm.	:	3 times each week for a total of 12 applications
Doses	:	200, 1000 and 2000 mg/kg
Control group	:	Yes
Year	:	1986
GLP	:	Yes
Test substance	:	Highly refined Base oil, Sample API 83-12 [CAS64742-53-6] See section 1.1.1.

Method : Undiluted API 83-12 was applied at doses of 200, 1000 and 2000 mg/kg/day to the shorn dorsal skin of groups of five male and five female rabbits. The test material was applied to the skin 3 times each week for 4 weeks (12 applications total). The applied material was covered with an occlusive dressing for 6 hours, which was then removed and the skin was
wiped with a dry gauze to remove any residual material. A group of five rabbits of each sex served as sham controls. The test skin site of each animal was examined and scored for irritation prior to each application of test material. Mortality and moribundity checks were performed twice daily and body weights were recorded weekly.
At termination, blood samples were taken for a range of hematological and clinical chemical measurements. Urine samples were also collected and frozen for possible future examination.
A complete gross necropsy was performed on all animals. Major organs were weighed and tissues were processed for subsequent histopathological examination.

Result : No deaths occurred during the study.
Skin irritation occurred to varying degrees in all animals treated with API 83-12. There was moderate irritation in the high dose males and females. In the mid dose group moderate irritation occurred in the females and slight irritation in the males. In the low dose group minimal irritation occurred in both sexes. The overall mean irritation scores were:

Dose level (mg/kg)	Males	Females
Control 0	0	0
200	0.1	0.4
1000	2.0	2.2
2000	2.6	3.1

Soft stool was also observed in several animals but this also occurred in a control male was not considered to be dose related. All high dose females appeared thin and this was considered to be treatment related.
Body weight gains were reduced in the high dose males and females and in the mid dose females when compared to their respective controls.
Overall weight changes (kg) are shown in the following table

Dose level (mg/kg)	Males	Females
Control 0	+0.5	+0.3
200	+0.3	+0.4
1000	+0.3	0.0*
2000	+0.1*	-0.2*

* statistically significant ($p \leq 0.05$)

Clinical chemical and hematological values were considered to be unaffected by treatment. A low value for white cell count in the low dose female group was considered incidental since the value was within a normal range and was not a dose-related effect.

Although there were some organ weight differences, they were considered incidental to treatment. The exception was for the absolute testis weights, which were lower in the high dose males and the relative weights of the right testis which were also lower than controls.

At gross necropsy, findings for the skin consisted of dry, scaly, rough, fissured, crusted and/or thickened skin. This was a common finding in all treatment groups.

Histopathological examination revealed slight to moderate proliferative changes in the skin in all rabbits in the high dose group. These changes were accompanied by an increased granulopoeisis of the bone marrow. The testes of 3 of the 5 males in the high dose group had bilateral diffuse tubular hypoplasia accompanied by aspermatogenesis and atrophy of the accessory sex organs. There were no changes observed in either the testes or epididymes of the male rabbits in the mid or low dose groups.
No other treatment-related histopathological changes were recorded.

Reliability : (1) Valid without restriction

(9)

Species	:	Rabbit
Route of admin.	:	Dermal
Test substance	:	Various Base oils
Remark	:	Data on repeated dose dermal studies in rabbits have been summarized elsewhere (CONCAWE 1997). The attached tabulated summary of information is taken from the CONCAWE publication.
Attached document	:	See Attachment 4. Summary of Repeated Dermal Studies with Base Oils (2) (3) (4) (5) (6) (7) (8) (14) (71) (108)
Species	:	Rat
Sex	:	Male/female
Strain	:	Fischer 344
Route of admin.	:	Oral feed
Exposure period	:	90 days
Frequency of treatm.	:	Continuous in food
Doses	:	0.002, 0.02, 0.2 & 2.0% in the diet
Control group	:	Yes
Method	:	OECD Guide-line 408 "Subchronic Oral Toxicity - Rodent: 90-day Study"
Year	:	1992
GLP	:	Yes
Test substance	:	White oil
Method	:	Three related, but separate studies were carried out at the same time on 6 different food grade white oils and 3 food grade waxes. Only the information on the oils is included here. The information on waxes is included in the Waxes and Related Materials HPV Test Plan. In the main study, groups of 20 male and 20 female rats were fed diets containing one of 6 different white oils at dietary concentrations of 0.002, 0.02, 0.2 and 2.0% for 90 days. Further groups of 60 male and 60 females were fed untreated control diet. Additionally groups of 20 rats of each sex were fed diets containing 2.0% coconut oil. The second study was a reversibility study. Groups of 10 rats of each sex were fed diets for 90 days containing one of the 6 different oils at the 2.0% level or coconut oil at 2%. These animals were then fed control diet for 28 days following the 90-days treatment. Groups of 30 rats of each sex served as controls for this reversibility study. A third study was designed to determine tissue levels of hydrocarbons. In this study, 5 rats of each sex were fed diets containing one of the 6 oils or coconut oil at the 2.0% dietary level for 90 days. Extra groups of rats (5 of each sex) were fed control diet or coconut oil or one of the six oils for 90 days followed by exposure to control diet only for a further 28 days.

In all three studies, animals were monitored for weight, food intakes and clinical condition throughout. An ophthalmic examination was performed prior to treatment and prior to necropsy on the animals in the main study and those for the study of reversibility.
A full necropsy was performed on the main and reversibility study animals and a full range of hematological parameters were measured on blood samples taken from the animals. Clinical chemical measurements were also made on serum separated from the blood samples. A selection of organs was weighed and a range of tissues retained for subsequent histopathological examination. All tissues from the high dose group and control groups were examined by light microscopy. Additionally the liver, lymph nodes, spleen, kidney, small intestine and lung were examined from all the intermediate dose groups.
Mineral hydrocarbon levels were measured in a limited number of tissues in those animals designated for tissue level determinations.

Remark : While only one report (three studies) is described here, numerous repeat dose studies on white oils destined for use in foods have been conducted and reported in the open literature.

Recent studies with a low molecular weight white oil have demonstrated that the F 344 rat is more sensitive in its response to mineral hydrocarbons than the Sprague Dawley rat (Firriolo et al). Indeed other studies on white oils with Sprague Dawley rats (McKee et al) and beagle dogs (Bird et al) have also not resulted in any reported effects.

Result : The six oils tested had average molecular weights ranging from 320 to 510. The effects observed in the study were inversely related to the oil's molecular weight. Thus the oil with the lowest molecular weight caused the most severe effects and at lower dose levels than the higher molecular weight materials. For simplicity, only the results of the highest and lowest molecular weight oils are summarized below. Furthermore, the results of the reversibility study are not given in detail here.
In general, there was evidence of reversibility of the effects but reversibility was not complete for all of the parameters measured.

P 100 H (Average molecular weight 510)

There were no treatment-related clinical signs, nor was there an effect on body weight. Food consumption was increased in the males of the highest dose group but this was less than 10% greater than for the controls. Ophthalmic examination did not reveal any effects. Organ weights, hematology and clinical chemistry were unaffected except for a 10% increase in ASAT in the males in the highest dose group.
There were no treatment-related findings at necropsy and the histological examination did not reveal any treatment-related effects.
A small amount of mineral hydrocarbon was found in the

livers of the male rats in the highest dose group.

N 10 A (Average molecular weight 320)

There were no treatment-related clinical signs, nor was there an effect on body weight. Food consumption was increased in the males of the highest dose group but this was less than 10% greater than for the controls. Ophthalmic examination did not reveal any effects.

Organ weights

Increases in organ weights are as shown below, other organ weights were unaffected.

Organ		Increases (%) at Dietary concentration			
		Males		Females	
		0.2%	2.0%	0.2%	2.0%
Kidney	(abs.)	4	6		5
	(rel.)		7		7
Liver	(abs)	8	11	6	21
	(rel.)	6	12	8	23
Spleen	(abs.)				17
	(rel.)		5		19
MLN*	(abs.)		224		220
	(rel.)		224		226

* Mesenteric Lymph Node weights only determined for the 2% dose group in the reversal group of animals and not for the main study animals.

Hematology

In the males in the highest dose group there were increases in Neutrophils (41%), monocytes (28%) and basophils (200%) In the females, changes occurred in the 2% and 0.2% dose groups. These were as follows:

	Change (% + or -) at dose level	
	0.2%	2%
RBC	- 2	- 3
Hemoglobin	- 2	- 3
WBC		+ 23
Differential WBC		
Neutrophils		+ 75
Monocytes		+ 51
Eosinophils		+ 38

Clinical chemistry

In the males there was a reduction in Alkaline phosphatase of
8 and 2% in the 2 and 0.2% dose groups respectively.
Changes in clinical chemical parameters in the females were as follows:

	Change (% + or -) at dose level	
	0.2%	2%
ALKP	- 12	- 13
ASAT		+ 12
Gamma GT		+ 91
A/G ratio		- 8

Histopathology

Liver
Liver lesions comprised mirogranuloma or granuloma, the distinction between being purely related to size. Lesions were classified as microgranuloma if the average diameter was less than 25% of the average hepatic lobule. The histological features of the two were similar and consisted of collections of macrophages, some with necrotic cells surrounded by inflammatory cells and variable fibrosis.

No lesions were observed in the males whereas granulomas were seen in the females in the highest dose group.
In females in the recovery group 28 days after cessation of exposure, the incidence was unchanged but the severity of the lesions had decreased.

Mesenteric Lymph node

The lymph node lesions comprised focal collections of macrophages, often in the cortical region. The macrophages were lightly vacuolated, giving a slightly foamy appearance to their cytoplasm. Some macrophages had a yellowish-brown pigmentation of varied intensity. The focal collections of macrophages were classified as histiocytosis and were scored as minimal, mild, moderate or marked based on size and abundance. The foci of histiocytosis were not homogeneously distributed; they were often restricted to one node or even to part of one node.
Histiocytosis was also found in control rats but was generally restricted to isolated foci and was always classified as minimal.
Compared to controls, in males histiocytosis increased down to the 0.2% dose group. In the females, histiocytosis was also observed in the 0.02% dose group.
In the reversibility group the severity and incidence was reduced after being fed control diet for 28 days.

Ileum and jejunum

There was a significant increase in vacuolation of the

lamina propria in the high dose female group.

In summary, the NOELs and LOELs for the six oils that were tested are as follows.

Oil	LOEL (histiocytosis) Dietary concentration	NOAEL
N10A	0.02%	
N15H	0.002%	
P15H	0.02%	
N70A	0.02%	
N70H	0.02%	
P100H	-	2.0%

Test substance : Six white oils examined in this study were characterized. Only the average molecular weight and viscosity at 100 °C are shown below:

Sample	Viscosity (cSt)	Average Molecular Weight
N10(A)	3.08	320
N15(H)	3.45	330
P15(H)	3.52	350
N70(A)	7.88	410
N70(H)	7.65	420
P100(H)	11	510

Reliability : (1) Valid without restriction

(20) (86) (93)

5.5 GENETIC TOXICITY 'IN VITRO'

Type : Modified Ames Assay
System of testing : Salmonella typhimurium strain TA98
Metabolic activation : With
Year : 1984
Test substance : Various base oils
The baseoils tested had PAC contents ranging from 0.2 to 12%. It is generally recognized that those base oils with PAC contents less than 3% are highly refined oils whereas those with greater values are considered to be poorly refined. This distinction was recognized and used by the EU in its classification of base oils. (Ref 70, 75)

Method : The method differed from the standard pre- incubation Ames assay in the following respects.

A DMSO extract of the test materials was tested in the assay.

The S9 fraction was obtained from Araclor-induced hamsters.

An eightfold concentration of S-9 was used in the assays.

Twofold concentration of cofactor NADP was used.

The DMSO extracts were tested over a range of concentrations that permitted the construction of a dose-response curve.

A Mutagenicity Index was determined for each assay. This was the tangent to the dose response curve at zero dose.

An assay was judged to be positive if the Mutagenicity Index was greater than 1.0

Result : Roy describes the mutagenicity results for a range of petroleum-derived materials, 28 of which were lubricating oil base stocks.
A Mutagenicity Index (MI) was determined for each test material and this was compared to the PAC content and to a carcinogenicity index that had also been determined for each material.
The results were as follows.

Sample	MI*	%PAC**	%T***	%T/LP****
5	0.9	0.9	0	4.17
6	0	0.3	0	0
7	0.9	0.9	2	4.17
8	0	0.6	0	0
9	0	0.3	0	0
10	0	0.7	2	3.28
12	2.4	3.1	4	5.93
13	9.1	10	26	71
14	0	0.7	2	3.45
15	0	0.2	0	0
16	3.9	3.7	6	1.6
17	4	3.1	8	14.3
18	3.6	4.9	10	21.7
19	6.5	5.2	10	23.4
20	9.2	7.7	40	138
26	0	0.5	2	2
27	0	0.5	2	3.92
28	0	0.3	0	0
29	0	0.6	0	0
30	0	0.6	0	0
32	10	12	54	154
33	5.9	7.8	42	73.7
34	4.1	4.1	50	104
35	1.2	1.2	4	6.25
36	2.1	1.5	18	38.3
37	0	0.7	2	2.13
38	4.5	4.6	24	46.2
39	0	1.2	0	0

* MI denotes Mutagenicity index.

** %PAC is weight % of 3-7 ring PNAs in the oil.

*** %T is the percentage of mice with tumors in skin carcinogenicity studies reported elsewhere.

**** %T/LP is the percentage of mice with tumors multiplied by the reciprocal of the latency period. The author describes this as a carcinogenic potency index.

Conclusion : Base stocks with no or low concentrations of PACs have low Mutagenicity indices. Also, those oils that were negative in the modified Ames assay (MI < 1.0) were not carcinogenic in mouse skin painting studies.

Those oils which were positive in the modified Ames assay had significant levels of PACs and were carcinogenic.

Reliability : (1) Valid without restriction

(22) (24) (98)

Type : Modified Ames Assay
System of testing : Salmonella typhimurium strain TA98
Metabolic activation : With
Result : Negative
GLP : No data
Test substance : Residual base oils

Method : The test substance (Canthus 1000, a deasphalted, dewaxed residual oil) was diluted 1:5 in DMSO and then shaken, centrifuged and separated into 2 fractions. Two assays were conducted for the test substance: an initial assay and a repeat assay. All plates were evaluated following approximately two days of incubation. Test volumes of 5, 10, 15, 20, 30, 40, 50 and 60 µl/plate were prepared by dilution of the DMSO fraction in DMSO and dosed at a final volume of 60 µl. The volumes were added to each plate with metabolic activation (hamster S9) and tester strain TA98 following the procedures outlined by Blackburn et al., (1986) and the methods described in the American Society for Testing Materials (ASTM) document, "The Standard Test Method for Determining Carcinogenic Potential of Virgin Base Oils in Metalworking Fluids". The same test volumes were used in the repeat assay.
A positive control and vehicle control were tested concurrently.

Linear regression analysis (ASTM: E 1687-95) was performed on the test substances which caused an increase in the mean number of revertant colonies when compared to the vehicle control. Only data from the linear portion of the dose response curve was used to generate the mutagenicity index (MI). If the increase in revertant colonies was not statistically significant or if there was no increase in the mean umber of revertant colonies, then the MI value was considered to be 0 (revertants/µl DMSO extract).

Data from both the initial and repeat assays on the test material (Canthus 1000) were pooled to generate a single linear MI value. With this procedure, an MI value > 1.0 (revertants/µl DMSO extract) is considered indicative of a potential dermal carcinogen in mice (Blackburn et al, 1996). Conversely, a test substance is considered unlikely to be carcinogenic in mouse skin when the MI value is < 1.0 (revertants/µl DMSO extract).

Result : The MI for Canthus 1000 was determined to be 0.2 revertants/µl DMSO extract.
Thus, under the conditions of this study, Canthus 1000 was considered negative for inducing frameshift mutations in Salmonella typhimurium.

Reliability : (4) Not assignable
This summary is based on a summary of the results of a study. It is not possible, therefore to assign a reliability to this study. The data however are useful, together with other similar data to demonstrate that residual base oils are not mutagenic in a modified Ames assay.

(18) (22) (23) (85)

Type : Modified Ames Assay
System of testing : Salmonella typhimurium strain TA98
Metabolic activation : With
Result : Negative

Remark : Summaries are available on Modified Ames assays that have been carried out on 3 additional residual base oils and a vacuum residuum.
The results and references to the studies are shown below.
Under the conditions of this study, the test materials were considered negative for inducing frameshift mutations in Salmonella typhimurium.

Material	Mutagenicity Index (MI)	Reference
Vacuum residuum	0.8	Petrolabs (1998)
Bright stock	0.11	Petrolabs (2000)
150 SUS Bright stock	0	EMBSI
150 Solvent Bright stock	0	EMBSI

Reliability : (4) Not assignable
This summary is based on a summary of the results of a study. It is not possible, therefore, to assign a reliability to this study. The data, however, are useful, together with other similar data, to demonstrate that residual base oils are not mutagenic in a modified Ames assay.

(74) (96) (97)

5.6 GENETIC TOXICITY 'IN VIVO'

Type : Cytogenetic assay
Species : Rat
Sex : Male/female
Strain : Sprague-Dawley
Route of admin. : gavage
Exposure period : 5 days
Doses : Ranged from 500 to 2000 and 500 to 5000 mg/kg

Method : A full description of the method is not given in the publication.
The publication includes the following information:

The rat bone marrow cytogenetics assay was performed after administration of each sample of the test materials to 5-10 males and 5-10 female Sprague Dawley rats per dose level. In gavage studies, the samples were dissolved in corn oil or saline and administered at a dosage of 5 ml/kg. Acute studies and 5-day subchronic tests were performed in the early stages of the work, but in subsequent assays only the subchronic test was performed.
A positive control chemical, triethylenemelamine (TEM) was tested concurrently.

Result : The results tabulated in the publication are as follows:

Sample	Dose (mg/kg)	No. animals	No. cells	Aberrant cells (%)
Paraffinic oils				
64 SUS	Corn oil	8	400	4.3
	500	10	500	3.8
	1000	9	450	2
	2000	10	500	2.8
133 SUS				
	Corn oil	10	500	3
	500	8	400	1.3
	1000	10	500	2
	2000	10	500	1
331 SUS				
	Corn oil	10	500	4
	500	9	450	3.8
	1000	8	450	5.6
	2000	10	500	7*
485 SUS				
	Corn oil	7	350	4
	500	9	450	4.9
	1000	8	400	4.3
	2000	7	350	5.7
990 SUS				
	Corn oil	8	400	1
	500	6	300	1.3
	1000	9	450	1.6
	2000	8	400	2.5
Naphthenic oils				
80 SUS	Saline	19	950	0.4
	500	17	850	0.4
	1670	19	950	0.6
	5000	20	1000	0.4
2000 SUS				
	Saline	19	950	0.7
	500	18	874	0.7
	1670	18	900	1.6
	5000	15	750	0.4
TEM				
	0.4-1.0			24.2-41.8*

* denotes significant by Wilcoxon rank test

Test substance : Two naphthenic and 5 paraffinic base stocks were tested. The characteristics of the samples tested are as follows:

Sample	Initial boiling point (° F)	Aromatics (%)	PNAs (%)
Paraffinic oils			
SUS at 100 °F			
64	536	10.2	0.4
133	639	13.8	0.7
331	636	28.1	3.0
485	572	27.8	4.1
990	515	31.9	4.8
Naphthenic oils			
SUS at 100 °F			
80	470	23.8	0.8
2000	611	37.7	4.5

Reliability : (4) Not assignable
The publication presents a summary of a program of work carried out for the API.
Since raw data are not presented in the publication, a reliability rating cannot be assigned.
Nevertheless, the information is useful in demonstrating the lack of in-vivo genotoxic activity of the base oils containing low levels of PACs.

(69)

5.7 CARCINOGENICITY

Species	:	Mouse
Sex	:	Male/female
Route of admin.	:	Dermal
Exposure period	:	Up to 84 weeks
Frequency of treatm.	:	Once or twice weekly
Doses	:	Various
Control group	:	Yes, concurrent no treatment
Test substance	:	Distillate base oils

Remark : Numerous skin carcinogenicity studies have been carried out on lubricating base oils derived from distillates. Data from these studies have been summarized and reviewed elsewhere.

No single study is summarized here but the general conclusions that may be drawn from the numerous studies are:

Highly refined base oils are not skin carcinogens.

Poorly refined or unrefined base oils are skin carcinogens.

A good correlation exists between skin carcinogenic potential and level of DMSO extractables and polycyclic aromatic compounds present in the base oil.

The degree of carcinogenicity is dependent on the level of polycyclic aromatic compounds present in the base oil.

When applied repeatedly to the skin, carcinogenic base oils are associated only with skin tumors and not with an increase in systemic tumors.

There is a good correlation between skin carcinogenicity and Mutagenicity Index as determined in a modified Ames assay.

(21) (24) (70) (71) (89) (98)

Species	:	Mouse
Sex	:	Female
Strain	:	CF No. 1
Route of admin.	:	Dermal
Exposure period	:	18 months
Frequency of treatm.	:	Three times weekly
Doses	:	0.1ml/application
Result	:	Negative
Control group	:	Yes
Year	:	1991
GLP	:	No data
Test substance	:	Residual base oils

Method : 0.01 ml of undiluted test material was spread three times weekly over the shorn dorsal skin of a group of 50 female CF No.1 mice. A further two groups of 5 female mice underwent

similar treatment and were killed after 22 or 52 weeks.

The appearance and development (or regression) of superficial tissue masses was recorded weekly throughout the study, to enable calculation of the latency period of those subsequently diagnosed as being tumors.

A positive control group of 50 female mice was treated with an oil (N1) that had been shown in previous studies to be a skin carcinogen. The mice in the positive control group received the oil once a week for 22 weeks and then once every 14 days for a total of 78 weeks.
A group of 50 untreated female mice served as negative controls.

Result : Minimal evidence of skin irritation was visible following treatment with the test materials.
No treatment-related effects were observed on clinical condition, body weight gain or mortality (NB survival rates for treated animals are not included in the report).
Changes recorded at post mortem were considered normal.
Histopathological examination of the skin of the treated mice provided no evidence of skin irritation and no tumors of epidermal origin were observed.

No cutaneous tumors were recorded in the group of untreated control mice (52% of animals survived to termination after 2 years)

The positive control group had skin reactions at the treatment site which included redness, scabbing, cracking and flaking; histopathological examination confirmed the presence of chronic inflammation (acanthosis, hyperkeratosis, ulcers, parakeratosis and scabs). In addition, skin reactions, principally at the margins of the treatment site were frequently recorded and were particularly seen during the first 22 weeks of treatment. These reactions typically included abrasions and ulceration. The severity of the lesions was such that many animals were killed on humane grounds; only 24% of animals survived to 78 weeks.
Histopathological examination of the skin revealed that over 78 weeks, 23 mice in the positive control group had 56 tumors of epidermal origin, of which 39 were benign (papillomas and keratoacanthomas) and 17 were malignant (squamous cell carcinomas and one single malignant basal cell tumor). The mean latency period was 37 weeks.

Test substance : The test substance was described as:
"A non-solvent refined, deasphalted, dewaxed residual paraffinic lubricant base oil"

Characteristic	Value
Kinematic viscosity	
at 40 °C	1024 cSt
at 60 ° C	266.6 cSt
at 100 ° C	42.52 cSt
Density at 15 ° C	0.9280 kg/l
Pour point	+3 ° C

Flash point (COC)	315 ° C
Refractive index	1.5142
Color (D1500)	8.0
Molecular weight (D2502)	660
Sulfur	1.7% wt
Aniline point	105.0 deg C
Volatiles 3 hrs at 13 ° C	0.10%
Neutralization value	0.02 mg KOH/g
Viscosity gravity constant (D2140)	0.846
Refractivity intercept	1.0598
Molecular type (D2007)	
Saturates	46.3% wt
Aromatics	45.6% wt
Polars	8.0% wt
Carbon type (D2140)	
C_A	15%
C_N	19%
C_P	66%

Total and individual PCA concentrations on completion of study

Individual PCA	mg/kg
Fluoranthene	0.2
Pyrene	0.9
Benz(a)anthracene	0.3
Chrysene/triphenylene	2.5
Benzofluoroanthenes	1.0
Benzo(e)pyrene	1.6
Benzo(a)pyrene	0.1
Perylene	0.1
Dibenz(a,j)anthracene	<0.1
Dibenz(a,h)anthracene	<0.1
Indeno(1,2,3-cd)pyrene	<0.1
Benzo(ghi)perylene	<0.1
Total PCA content (BP3 method)	7.0% wt

Reliability : (4) Not assignable
This report is a summary report and as a consequence does not provide full experimental details, but does provide sufficient information for a conclusion to be made on the skin carcinogenic potential of a non-solvent refined residual paraffinic base oil.

(91)

Species : Mouse
Sex : Male
Strain : C3H
Route of admin. : Dermal
Frequency of treatm. : 3 times weekly
Post exposure period :
Doses : 25 µl per application
Result : Negative
Control group : Yes
GLP : No data
Test substance : Canthus 210 a Deasphalted, dewaxed, residual oil

Method : The summary states that the design of the study was similar to other conventional skin painting studies in mice.

The test material was applied undiluted in 25 µl aliquots to the clipped dorsal back regions of 50 male C3H/HeJ mice, three times weekly. At each treatment period, the dorsal skin was examined for the presence of papillomas/carcinomas, and each animal was also examined daily for any clinical signs of ill health. Treatment continued for 24 months. A complete necropsy was conducted at the time of sacrifice. In this study, Primol 185, a medicinal grade white mineral oil was applied undiluted and served as the negative control. Heavy Clarified Oil (HCO) was applied as a 10% solution in Primol 185, and served as the positive control.

Result : None of the animals treated with the test material or the negative control material developed skin tumors, or any other tumors considered treatment-related, over the course of the study. The positive control material, 10% HCO, responded as anticipated, producing squamous cell carcinomas in 47 of 50 treated animals.

Reliability : (4) Not assignable
The information given is based on a summary of the study and hence it is not possible to assign reliability to the study. Nevertheless, the data provide useful information on the carcinogenic potential of residual base oils.

(76)

Species : Rat
Sex : Male/female
Strain : Fischer 344
Route of admin. : Oral feed
Exposure period : 2 years
Frequency of treatm. : Daily in the diet
Doses : 60, 120, 240 and 1200 mg/kg/day
Result : Negative
Control group : Yes
Method : OECD Guide-line 453 "Combined Chronic Toxicity/Carcinogenicity Studies"
Year : 2001
GLP : Yes
Test substance : White oil

Remark : This study is a study that was conducted according to OECD guidelines. It is not described in full in this summary since it is not one of the SIDS base set requirements.

Result : Survival was unaffected by exposure to the test material. There were no treatment related clinical signs, or any effects on body weight, food consumption, food conversion efficiency or ophthalmology. Furthermore, there was no treatment related effects on the hematological, serum chemistry or urinalysis parameters that were measured. At gross necropsy, there were no treatment-related gross observations and there were no treatment-related neoplastic changes.

Test substance : The test material is a 70 cSt white oil with an average molecular weight of 485.

Reliability : (1) Valid without restriction

(84)

Species	:	Rat
Sex	:	Male/female
Strain	:	Fischer 344
Route of admin.	:	Oral feed
Exposure period	:	104 weeks
Frequency of treatm.	:	Continuous in the feed
Doses	:	2.5 and 5% in the diet
Result	:	Negative
Control group	:	Yes
Year	:	1997

Result :

There were slight increases in body weights in both sexes of the 5% group (5% for males and 2.7% for females) at week 104. Food consumption was also increased in the 5% groups (11% for males and 8% for females total increase at week 104). However, no significant treatment-related differences between the control and treated groups were observed for clinical signs, mortality or hematological findings.
In the 5% group, absolute liver and kidney weights were increased in males and absolute and relative submaxillary gland weight were reduced in females. Absolute and relative weights of heart and spleen were unaffected by treatment.
The percentage increases/decreases in the 5% group were:

Organ	Absolute	Relative
Female		
Submaxillary gland	3% decrease	1.7% decrease
Male		
Liver	8.4% increase	not different
Kidney (R)	14.9% increase	not different
Kidney (L)	9.9% increase	not different

In the 5% male group, the increased absolute organ weights were attributed to the slight increases in body weights.

A variety of tumors developed in all groups, including the control group. However, all the neoplastic lesions were histologically similar to those known to occur spontaneously in F344 rats, and no statistically significant increase in the incidence of any tumor type was found for either sex in the treated groups.

Granulomatous inflammation in the mesenteric lymph nodes, considered to be a reaction to paraffin absorption, was observed with similar incidence and severity in both sexes of the 2.5 and 5% groups.

The authors concluded that under the present experimental conditions, the high dose, about 2000-200,000 times higher than the current temporary acceptable daily intake, did not have any carcinogenic potential in F344 rats. Furthermore, the granulomatous inflammation observed in the mesenteric lymph nodes was not associated with any development of

neoplastic lesions.

Test substance : The test material was composed of equal quantities of eight different commercially available liquid paraffins (highly refined white oils) obtained from eight member companies of the Japan Liquid Paraffin Industry.
Each of the eight liquid paraffins complied with the requirements of the Japanese food additive and Japanese Pharmacopoeia standards. 5 of the component material had been derived from petroleum by acid treatment and the other eight had been derived by hydrotreatment.
The physical properties of a sample of the composite test material were determined by CONCAWE and were as follows:

Viscosity at 40°C	0.871
Viscosity at 100 °C	8.68
Ratio of naphthenic/paraffinic hydrocarbon	35/65
Average molecular weight	475
Carbon No. at 5% boiling point	25

Reliability : (2) Valid with restrictions
Although the experimental details are not provided here, the information is nevertheless useful in establishing the lack of carcinogenicity by the oral route.

(105)

5.8.1 TOXICITY TO FERTILITY

Type : One generation study
Species : Rat
Sex : Male/female
Strain : Sprague-Dawley
Route of admin. : Gavage
Frequency of treatm. : Daily
Doses : 1.15 mg/kg
Control group : No
Method : OECD Guideline 421, Reproductive/Developmental Toxicity screening test
Year : 1995
GLP : Yes
Test substance : Chevron 100 neutral (refined) CAS 64742-54-7

Method : The method used was as described in OECD guideline 421.

The base oil was administered by gavage at a dose of 1.15 mg/kg (bw) to a group of 12 male and 12 female Sprague Dawley
rats. Rats designated F0 animals were dosed for a minimum of 14 days prior to mating. Dosing was continued after mating until a total dosing period of 30 days had elapsed for males and until day 4 of lactation for females (39 days).
The animals were observed twice daily for appearance, behavior, moribundity and mortality. Males and females were also observed during dosing and for one hour thereafter.
Male F0 body weights were recorded weekly. Female F0 body weights were also recorded weekly until evidence of mating was observed and then on gestation days 0, 7, 14 and 20 and on lactation days 1 and 4. Food consumption was also

recorded for F0 both sexes.
Animals were paired on a 1:1 basis. Positive evidence of mating was confirmed either by the presence of sperm in a vaginal smear or a vaginal plug. The day when evidence of mating was identified was termed Day 0 of gestation.

The following Fertility indices were calculated:
Female mating index
Male mating index
Female fertility index
Male fertility index

All females were allowed to deliver their young naturally and rear them to post-natal day 4. Females were observed twice daily during the period of expected parturition for initiation and completion of parturition and for signs of dystocia. After parturition, litters were sexed and examined for evidence of gross malformations, numbers of stillborn and live pups.
Litters were examined daily and each pup received a detailed physical examination on days 1 and 4 of lactation. Any abnormalities were recorded.
The live litter size and viability index were calculated.
All surviving pups were necropsied on post-natal day 4.
A complete gross examination was made on all animals at necropsy.
Selected organs of parental animals were weighed and a wide range of tissues was fixed for subsequent histopathological examination.

Result : Only the results for the base oil control group are reported below.

There were no clinical findings and growth rates and food consumption values were normal.
Fertility indices and mating indices for males and females were both 100%.
At necropsy, there were no consistent findings and the animals were considered to be normal.
Organ weights and histopathology was considered normal.

Reliability : (2) Valid with restrictions
The study was on an oil additive in base oil at two concentrations. The base oil alone was used as the control. Therefore, no control was available with which to compare the
study control group. However, since all the recorded values were within normal limits, it could be concluded that the base oil was without effect.

(113)

Type	:	One generation study
Species	:	Rat
Sex	:	Male/female
Strain	:	Sprague-Dawley
Route of admin.	:	Gavage
Exposure period	:	13 weeks prior to mating
Frequency of treatm.	:	5 times weekly
Male	:	13 weeks
Female	:	13 weeks
Duration of test	:	One generation after 13 weeks dosing
No. of generation studies	:	1
Doses	:	5 ml/kg
Control group	:	No
Year	:	1987
GLP	:	No data
Test substance	:	White oil CAS 8012-95-1

Method : 72 female and 36 male Sprague-Dawley rats were given white oil at a dose of 5 ml/kg, 5 days a week for 13 weeks. After this time each of the males was housed with 2 females for 10 consecutive nights, or until mating was confirmed by the appearance of a copulatory plug or by the presence of sperm in a vaginal rinse.
The mated females were maintained without further dosing through gestation and lactation to post-partum day 21.
Detailed maternal physical examinations and body weight measurements were made on days 0, 7, 14 and 21 of gestation and on days 0, 4, 14 and 21 of lactation.
All dams and surviving litters were sacrificed and grossly examined on day 21 of lactation. Each of the offspring was examined for external malformations. All pups were then sacrificed, necropsied and subjected to visceral organ and brain examination. Pups which died spontaneously were also necropsied unless this was precluded by cannibalism or autolysis.

Remark : White oil was used as solvent control in a study to determine the effects of two EDS coal liquids in a 13 week subchronic a single generation reproduction study. There were three dose groups and a control group for each test material in this study. The information in this robust summary relates only to the white oil control groups (one for each of the test materials) and NOT to the groups exposed to EDS coal liquids.

The CAS# for the material that was used in this study is not included in the Lubricating Base Stocks category. However, because white oils are so highly purified, toxicologically and compositionally they are all very similar. Therefore, the Testing Group thinks the results on CAS # 8012-95-1 are applicable to the highly refined base oils that are included in this category.

Result : The data for the two control groups are summarized below.

Parameter	Control 1	Control 2
Impregnation frequency	80.8%	80.9

Gestation	22.6 days	22.6
Pups delivered	11.7	11.1
Live births	11.2	10.7
Survival at day 4	10.5	9.6
Survival at day 14	10.2	9.3
Survival at day 21	10.1	9.3
Offspring body weights		
Day 0 lactation	6.7	6.9
Day 4 lactation	9.3	9.9
Day 14 lactation	26.9	27.1
Day 21 lactation	43.2	46.7

No unusual behavior was reported during the gestation period for either of the control groups.
The general condition of offspring and dams was good through weaning.
Gross observations of pups and dams were generally unremarkable.
In one base oil group, 3 malformed pups were found in 2 litters. Two of the malformed pups had syndactyly and renal agenesis and one of these also exhibited agnathia. The third pup had a small eye.

In the other control group, four malformed pups were found in 4 litters. Two of the pups had tail abnormalities, one had a
depression in the sternum and the fourth had a short snout.

The authors comment that a similar spectrum of malformations in Sprague-Dawley rats from the same supplier has been reported elsewhere. The authors also comment that this spectrum of malformations can occur spontaneously in the Sprague-Dawley rat and are not regarded as treatment-related.

Reliability : (2) Valid with restrictions
Not all the raw data are presented in this publication. However, the data are useful in determining that white oils do not cause effects on reproduction after prior exposure for 13 weeks.

(93)

5.8.2 DEVELOPMENTAL TOXICITY/TERATOGENICITY

Species	:	Rat
Sex	:	Female
Strain	:	Sprague-Dawley
Route of admin.	:	Gavage
Exposure period	:	Days 6 through 19 of gestation
Frequency of treatm.	:	Daily
Year	:	1987
GLP	:	No data
Test substance	:	White oil CAS 8012-95-1

Method : Two groups of animals (50 and 25) were administered white oil by gavage at a dose of 5 ml/kg, every day during gestation days 6 to 19 inclusive. Food and water were available continuously. Animals were examined for viability and clinical effects twice daily. Body weights were recorded on days 0, 6, 10 and 20 of gestation.
On day 20 of gestation, all animals were euthanized with methoxyfluorane and examined for gross changes. Each gravid uterus was removed and weighed. The number, location and viability of each fetus and the number of implant sites were recorded. Fetuses were removed, weighed and the crown-rump lengths measured. All live and dead fetuses that had not been resorbed were examined for external malformations. Approximately half of the fetuses from each litter were decapitated and the heads preserved for subsequent examination for abnormalities. The viscera were also examined for malformations under low power magnification. The remaining fetuses were stained with Alizarin red and subsequently examined for skeletal abnormalities.
No organs, other than the uteri were weighed and no organs were examined histologically in this study.

Remark : White oil was used as the solvent control in two separate studies, one for each of two test materials.
This summary only reports on the outcome of the animals in the two control groups.

The CAS# for the material that was used in this study is not included in the Lubricating Base Stocks category. However, because white oils are so highly purified, toxicologically and compositionally they are all very similar. Therefore, the Testing Group thinks the results on CAS # 8012-95-1 are applicable to the highly refined base oils that are included in this category.

Result : One animal died in the control group containing 50 animals and this was attributable to mis-dosing.
Increases in body weight during the study were considered normal. These with other recorded parameters are summarized in the table below.

Day of gestation	**Group 1 (25 rats)**	**Group 2 (50 rats)**
Body weights (g)		
0	207.2	225.4

6	227.5	248
10	235.9	259.3
15	260	284.3
20	329.1	351.9
Uterine wt	67.2	70.7
Number of litters	25	49
Implants/litter	11.3	12.0
Resorptions/litter	0.06	0.47
Males		
No./litter	5.12	5.96
Crown-rump length (mm)	3.66	3.6
Wt. of fetuses	4.26	4.23
Females		
No./litter	5.6	5.61
Crown-rump length (mm)	3.61	3.52
Wt. of fetuses	4.02	4.07

In the control group containing 50 animals, 3 malformed fetuses were found in 3 litters; one had an extra lumbar vertebra, one had a discrete area of ossification in the area
of the junction of the frontal and nasal bones, one had moderately dilated lateral ventricles of the brain.

3 malformed fetuses were also found in 3 litters of the other control group. These were, a vertebral arterial canal of a cervical process fully ossified in 2 fetuses and angulated ribs in a third fetus.

The authors considered these malformations to be minor and that the findings were within the normal ranges for the strain of rat.

Reliability : (2) Valid with restrictions
Although there were no untreated animals for comparison, the results were nevertheless, considered to be within normal limits. Consequently, the study is useful in providing evidence of the lack of developmental effects for white oil.

(92)

5.11 ADDITIONAL REMARKS

Type : Correlation of toxicity with chemical components of refinery streams

Remark : Heavy vacuum gas oil is used as a starting material for base oil production. As such, it can be considered a "worst case" example of the unrefined/mildly refined base oil subcategory. Studies on this material are summarized below.

Type : 90-day study on Heavy vacuum gas oil

Method : Undiluted heavy vacuum gas oil was applied at doses of 0,

30, 125, 500 and 2000 mg/kg/day to the shorn skin of groups of ten male and ten female Sprague Dawley rats. The material was applied 5 days each week for 13 weeks. Collars were fitted to the animals to prevent oral ingestion.
Body weights were recorded weekly throughout the study and clinical observations were made daily. Skin irritation was assessed weekly. At 5 and 13 weeks blood samples were taken for hematological and clinical chemical analyses. At the end of the study (13 weeks) all surviving animals were sacrificed and a gross necropsy examination was performed. 20 tissues were preserved for subsequent histopathological examination.

Result : Two males and one female in the high dose group died during the study. The male deaths were considered to be compound related but the female death was considered incidental.
Growth rates of males and females in the highest dose group were reduced compared to controls. At 13 weeks the males weighed 20% less and the females 15% less than controls.
At 2000 mg/kg/day males and females had reduced erythrocytes and reduced platelets at 5 and 13 weeks. Similar effects were also found in the 500 mg/kg/day females.

Clinical chemical changes in males and females at 2000 mg/kg/day consisted of:

- twofold increase in sorbitol dehydrogenase
- twofold increase in cholesterol
- 50% reduction in uric acid

In addition in females at 500 mg/kg/day, glucose was reduced and in the 500 mg/kg males cholesterol was increased.

At gross necropsy, relative thymus weights were reduced in the 500 (by 25%) and 2000 mg/kg/day (by 50%) animals of both sexes. Relative liver weights were also increased at 500 and 2000 mg/kg/day for both sexes.

Histological examination revealed decreased erythropoeisis and fibrosis of the bone marrow in the 2000 mg/kg/day males. There was a reduction in thymic lymphocytes in the 2000 mg/kg/day groups (marked for males and moderate for females) and a slight reduction in the 500 mg/kg/day groups for both sexes.

No effects were found on either sperm morphology or in the results of the urinalysis.

The NOEL for both males and females was found to be 125 mg/kg/day.

Reliability : (2) Valid with restrictions
The report evaluated was incomplete but nevertheless was sufficient to identify the relevant effects of exposure to the test material.

(94)

Type : Developmental toxicity screen on Heavy vacuum gas oil

Method : Groups of 10 presumed-pregnant rats were distributed into the

following groups:

Group	Dose level (mg/kg/day)	Gestation days of administration
1	0 (remote control)	0-19
2	0 (proximate control)	0-19
3	30	0-19
4	125	0-19
5	500	0-19
6	1000	0-19
7*	500 (bioavailability)	10-12

* Group size was 5 at start but increased to 8 after study initiation.

The test material was applied daily to the shorn dorsal skin at the dose levels shown above and for the duration indicated. The rats were fitted with collars to prevent oral ingestion of the applied material.
Since it was believed that inhalation of test material could be a confounding factor a second group of controls (remote controls) were housed in an area in which they could not inhale gasoil that had been applied to other animals.

Observations were made daily for clinical signs and body weights and food consumption were recorded regularly throughout the study.

Each female was sacrificed on day 20 of presumed gestation and the thoracic and abdominal cavities were examined grossly.
The thymus and liver were removed from each animal and weighed and then preserved in formalin but not examined further.
The uterus and ovaries were removed and examined grossly. The number of corpora lutea per ovary for each rat was recorded. The ovaries of non-pregnant females were examined and then discarded. Uterus weights were also determined.
The uterine contents of each pregnant rat were exposed and a record made of the number and location of all implantations.
At necropsy, blood samples were taken from all the animals and a range of clinical chemical measurements were made.
Fetuses were examined and half were preserved for examination of soft tissue abnormalities, the remainder being differentially stained for skeletal examination.

Result : Parental animals.

There were no clinical signs attributable to exposure to HVGO other than in the highest dose group in which 2 rats had a red vaginal discharge, one animal was pale in color and six had decreased stool. The latter observation was probably associated with a smaller food consumption in this group. Although food consumption was generally also less than controls in the 500 mg/kg/day group there was no associated body weight decrease.
At doses in excess of 125 mg/kg/day there was a decrease in

mean body weights which reflected the decreased litter sizes for this group.
The only dose-related finding at gross necropsy was a pale appearance of lungs in a few animals. 4 animals were affected at the highest dose and only one in the 500 mg/kg/day group.
Mean thymus weights of animals in the highest dose group were approximately half those of the control groups.
Although absolute liver weights were unaffected by exposure to HVGO, mean relative liver weights were increased (approximately 15%) in groups exposed to doses greater than 125 mg/kg/day.

Observations of Dams at Caesarean section.

Parameters with treatment-related effects are shown below.

	Dose group (mg/kg/day)					
	0(R)	**0(P)**	**30**	**125**	**500**	**1000**
Pregnant females						
	9	10	10	8	10	9
Dams with viable fetuses						
	9	10	10	8	10	6
Dams with all resorptions						
	0	0	0	0	0	3
Mean litter size of viable fetuses						
	13.9	14	13.8	14.4	10	5.8
Resorptions						
Mean	1.1	0.6	1.1	1.1	5.6	9.9
% Dams with resorptions						
	56	50	70	63	100	100

Parameters unaffected were:
- No. premature births
- Female mortality
- No. corporea lutea
- No. implantation sites
- Pre-implantation losses
- Viable male fetuses
- Viable female fetuses
- No. dead fetuses

Fetal evaluations

fetal body weights were significantly reduced in fetuses exposed in utero to HVGO at doses in excess of 125 mg/kg/day.
Although there were differences between control and treated crown-rump lengths they were not statistically significant.
At the time of external examination, malformations were observed in one fetus in the 1000 mg/kg/day group. The fetus was edematous and pale in color. Both hindpaws were malformed; the digits were reduced in size with a subcutaneous hematoma located at the distal most aspect of each of the digits.
Malformations of the vertebral column were restricted to the

500 mg/kg/day group.
Although a variety of skeletal malformations were observed in treated and control groups the degree of aberrant development in control fetuses was not as severe as in the HVGO-exposed groups.
Visceral malformations were restricted to two fetuses in the 500 mg/kg/day group. One fetus had microphthalmia and the other fetus had a diaphragmatic hernia which displaced the heart from the left to right hand side.

Test substance : Heavy vacuum gasoil CAS 64741-57-7

Reliability : (2) Valid with restrictions
The report evaluated was incomplete but nevertheless was sufficient to identify the relevant effects of exposure to the test material.

(95)

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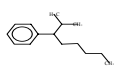
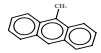
Attachment 1. Physico-chemical properties for selected lubricating oil basestocks

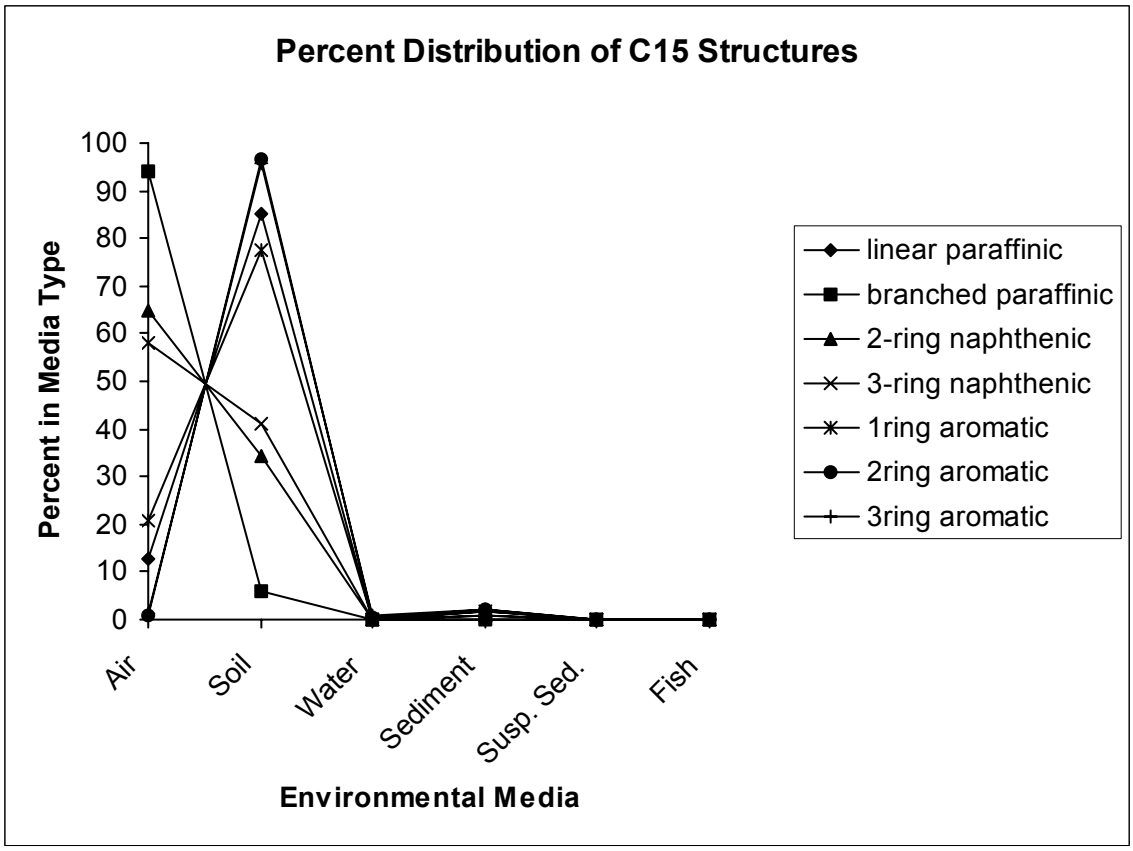
Base oil description	Kinematic viscosity * at 40^{0}C (mm^2/s) ASTM D445	Kinematic viscosity * at 100^{0}C (mm^2/s) ASTM D445	Flash Point (^{0}C) ASTM D93	Pour Point (^{0}C) ASTM D97	Density (kg/l) ISO 12185	Average Molecular Weight ASTM D2502
Distillate oils						
White mineral oil (8042-47-5)	27.3	5.0	217	-15	0.86	400
Residual oils						
Solvent-dewaxed (64742-62-7)	1300	50	285	-6	0.95	700

*Kinematic viscosity is often expressed in Centistokes (cSt). It should be noted that 1 cSt = 1mm^2/second.

Attachment 2. EQC Modeling Results of the Distribution Between Environmental Compartments

		Percent Distribution - EQC Model					
Structure		**Air**	**Soil**	**Water**	**Sediment**	**Susp. Sed.**	**Fish**
C15 linear paraffin		1.3E+01	8.5E+01	1.9E-03	1.9E+00	5.9E-02	4.8E-03
C15 branched paraffin		9.4E+01	5.8E+00	2.8E-04	1.3E-01	4.1E-03	3.3E-04
C15 2-ring naphthene		6.5E+01	3.4E+01	1.4E-02	7.6E-01	2.4E-02	1.9E-03
C15 3-ring naphthene		5.8E+01	4.1E+01	1.1E-01	9.1E-01	2.9E-02	2.3E-03
C15 1ring aromatic		2.1E+01	7.8E+01	4.2E-02	1.7E+00	5.4E-02	4.4E-03
C15 2ring aromatic		8.6E-01	9.7E+01	2.3E-01	2.1E+00	6.7E-02	5.5E-03
C15 2ring aromatic		4.4E-01	9.7E+01	1.4E-01	2.2E+00	6.8E-02	5.5E-03
C15 3ring aromatic		1.2E+00	9.6E+01	9.2E-01	2.1E+00	6.6E-02	5.4E-03
C15 3ring aromatic		1.5E+00	9.5E+01	8.8E-01	2.1E+00	6.6E-02	5.4E-03

Attachment 3. Plot of the EQC Modeling Results of the Distribution Between Environmental Compartments



Attachment 4. Summary of Repeated Dermal Studies with Base Oils

Material	Duration	Dose (mg/kg)	Effects on skin	*Systemic effects*	API Report No.
Paraffinic distillates					
Unrefined API 84-01	28 days 3 doses per week	2000	Moderate irritation Proliferative changes	Marginal body weight decrease	33-31642
		1000	Slight irritation	None observed	
		200	Minimal irritation	None observed	
Solvent dewaxed, light API 78-9	21 days 4h/day 3 days/week	5000	Acanthosis, parakeratosis Chronic dermal inflammation	None observed	29-33065
Solvent dewaxed, heavy API 78-10*	"	5000	Acanthosis, parakeratosis Chronic dermal inflammation	None observed	29-33105
79-3	"	5000	None	None observed	29-33067
79-4	"	5000	None	None observed	29-33066
79-5	"	5000	None	None observed	29-33068
5 Paraffinic base oils	28 days 5 days per week	1000	Minor irritation	None observed	Trimmer et al, 1989
Naphthenic distillates					
Solvent refined, light API 78-5	"	5000	Acanthosis, parakeratosis Chronic dermal inflammation	None observed	29-33106
API 79-1	"	5000	None	None observed	29-33065
Hydrotreated, light API 83-12	28 days 3 doses per week	2000	Moderate irritation	Reduced testis weight	33-30499
		1000	Males: slight irritation Females: moderate irritation	None observed	
		200	Minimal irritation	None observed	
Hydrotreated, heavy API 83-15	28 days 3 doses per week	2000	Slight irritation hyperplasia	Elevated SGOT & SGPT, decreased body weight. Subacute hepatitis. Increased relative liver weight in females	35-32430
		1000	Slight irritation	Elevated SGOT & SGPT	
		200	Minimal irritation	None observed	

* Although this material is not included in the HPV Lubricating base stocks category, it is similar to other materials in the category and provides supportive information

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F009 A35-01
EOR
F001 40
F002 1
F003 Baseoils
F012 Y
F010 16-02-2003
F004 12031538
F005 24-07-2001
F006 12031538
F007 24-07-2001
F008 Baseoils
F009 A35-01
EOB
C
B115 GI_COMPANY_TAB
F001 40
F002 1
F003 17-09-2010
F004 IUC4
F020 A36-003
EOB
C
B101 GI_GENERAL_INFORM_TAB
F001 40
F002 1
F003 24-03-2003
F004 IUC4
F010 A04-06
F011 A19-02
EOB
C
B109 GI_EXPO_LIMIT_TAB
F001 40
F002 1
F003 09-09-2002
F004 IUC4
F007 A17-07
F008 5
F009 A16-03
F010 10
F011 A16-03
EOB
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C
B126 GI_ADD_REVIEWS_TAB
F001 40
F002 1
F003 23-09-2001
F004 IUC31
F007 IARC reviewed, in 1984, the carcinogenicity information on lubricating
*    base oils and the outcome of their review was published in a Monograph.
EOR
F001 40
F002 3
F003 09-08-2001
F004 IUC31
F007 Bingham reviewed the literature for information on the carcinogenic
*    potential of petroleum hydrocarbons. This review contained information on
*    base oils.
EOR
F001 40
F002 4
F003 26-08-2002
F004 IUC4
F007 CONCAWE demonstrated that it was possible to distinguish between
*    carcinogenic and non-carcinogenic base oils on the basis of the level of
*    DMSO extractables. This approach was subsequently adopted in the EU for
*    classification purposes.
EOR
F001 40
F002 5
F003 26-08-2002
F004 IUC4
F007 The EU Scientific Committee for Food (SCF)  and the WHO Joint Expert
*    Committee on Food Additives (JECFA) have reviewed the available data on
*    the toxicology of mineral hydrocarbons for food uses.
EOR
F001 40
F002 6
F003 11-10-2002
F004 IUC4
F007 The WHO published an Environmental Health Criteria document which
*    included summarized information on lubricating base oil stocks
EOB
C
B201 PC_MELTING_TAB
F001 40
F002 1
F003 12-11-2002
F004 IUC4
F015 A36-003
F012 P01-03:ASTM D97
F014 A03-02
F020 A01-03:Lubricating Base Oils; distillate oils, residual oils, and white
*    oilsVarious
EOB
C
B202 PC_BOILING_TAB
F001 40
F002 1
```

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F003 12-11-2002
F004 IUC4
F016 A36-003
F013 P03-03:Calculated by: MPBPWIN V1.40 (EPIWIN V3.10; US EPA 2000)
F015 A03-01
F018 A01-03:American Society for Testing and Materials (ASTM). 2002. Standard
*    Test Method for Pour Point of Petroleum Products (Rotational Method).
*    ASTM D5985-02, Volume 05.01, ASTM, West Conshohocken, PA.
EOB
C
B204 PC_VAPOUR_TAB
F001 40
F002 1
F003 13-02-2003
F004 IUC4
F015 A36-002
F011 25
F012 P06-01
F013 1991
F014 A03-03
F018 A01-03:CAS No. 64742-65-0, Distillates (petroleum), solvent-dewaxed,
*    paraffinic
EOB
C
B301 EN_PHOTODEGRADATION_TAB
F001 40
F002 1
F003 06-09-2002
F004 IUC4
F045 A36-003
F007 A01-03: CAS No.: Various; Unrefined and acid treated base oils.
F009 F02-05: Calculations by EPIWIN V3.10; AOPWIN V1.90.
F010 2001
F043 A03-01
EOB
C
B302 EN_STABILITY_IN_WATER_TAB
F001 40
F002 1
F003 02-02-2002
F004 IUC31
F040 A36-002
F039 A03-01
EOB
C
B305 EN_TRANSPORT_TAB
F001 40
F002 2
F003 23-12-2002
F004 IUC4
F011 A36-003
F007 F20-04: Mathematical computer model
F008 F22-01: Soil, air, water, suspended sediment and sediment for C15
*    hydrocarbon structures
F009 F21-01: Calculations by EQC V2.11
F010 1999
EOB
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C
B308 EN_BIODEGRADATION_TAB
F001 40
F002 1
F003 06-09-2002
F004 IUC4
F047 A36-003
F048 1
F007 A01-03: CAS No. 64742-65-0; Distillates (petroleum), solvent-dewaxed
*    heavy paraffinic
F008 F25-01
F009 F26-03
F010 1986
F011 F27-0166: Microorganisms were obtained from Canterbury Sewage Works (UK)
*    and prepared according to the prescribed methods for this test.
F046 A03-03
F052 28
F053 F05-01
EOR
F001 40
F002 3
F003 09-09-2002
F004 IUC4
F047 A36-002
F048 2
F007 A01-03: CAS No. 64742-54-7; Distillates (petroleum), hydrotreated heavy
*    paraffinic
F008 F25-01
F009 F26-20
F010 1995
F011 F27-0139
F046 A03-03
F052 28
F053 F05-01
EOR
F001 40
F002 7
F003 09-09-2002
F004 IUC4
F047 A36-003
F048 3
F007 A01-03: CAS No. 64741-89-5; distillates (petroleum), solvent-refined,
*    light paraffinic
F008 F25-01
F009 F26-16
F010 1990
F011 F27-0139
F046 A03-03
F052 28
F053 F05-01
EOR
F001 40
F002 18
F003 11-09-2010
F004 IUC4
F047 A36-003
F048 4
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F007 A01-03: CAS No. 64741-89-5; distillates (petroleum), solvent-refined,
*    light paraffinic
F008 F25-01
F009 F26-25: CEC Method L-33-T-82 using test medium from ISO Standard 7827 and
*    OECD 301A and 301E
F010 1991
F011 F27-0139
F046 A03-03
F052 21
F053 F05-01
EOR
F001 40
F002 31
F003 16-02-2003
F004 IUC4
F048 5
F007 A01-03: Various base oils
F008 F25-01
EOB
C
B401 EC_FISHTOX_TAB
F001 40
F002 1
F003 17-09-2010
F004 IUC4
F033 A36-003
F034 1
F007 A01-03: CAS No. 64741-89-5; distillates (petroleum), solvent-refined,
*    light paraffinic
F008 E01-04
F009 E02-0139
F010 E03-03
F011 1990
F012 96
F013 E04-02
F014 E05-02
F031 A03-03
F032 A03-03
F050 C47-002
EOR
F001 40
F002 15
F003 30-12-2002
F004 IUC4
F007 A01-03: Various base oils
F010 E03-05: Acute toxicity tests
EOB
C
B402 EC_DAPHNIATOX_TAB
F001 40
F002 1
F003 11-09-2010
F004 IUC4
F032 A36-003
F033 1
F007 A01-03: CAS No. 64742-53-6 or 64741-97-5, Distillates (petroleum),
*    hydrotreated or solvent-refined light naphthenic
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F008 E06-0010
F010 1988
F011 48
F012 E04-02
F013 E05-02
F030 A03-01
F031 A03-01
F042 E01-05
EOR
F001 40
F002 2
F003 11-09-2010
F004 IUC4
F032 A36-003
F033 2
F007 A01-03: CAS No. 64742-53-6 or 64741-97-5, Distillates (petroleum),
*    hydrotreated or solvent-refined light naphthenic
F008 E06-0020
F010 1988
F011 96
F012 E04-02
F013 E05-02
F030 A03-01
F031 A03-01
F042 E01-04
EOB
C
B403 EC_ALGAETOX_TAB
F001 40
F002 1
F003 30-12-2002
F004 IUC4
F036 A36-003
F037 1
F007 A01-03: CAS No. 64741-88-4; distillates (petroleum), solvent-refined,
*    heavy paraffinic
F008 E08-0055
F009 E09-03
F010 1991
F011 E10-02
F012 96
F013 E04-02
F014 E05-02
F034 A03-03
F035 A03-03
F054 C47-002
EOB
C
B406 EC_CHRONDAPHNIATOX_TAB
F001 40
F002 1
F003 09-09-2002
F004 IUC4
F030 A36-003
F031 1
F007 A01-03: CAS No. 64741-88-4; distillates (petroleum), solvent-refined,
*    heavy paraffinic
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F008 E06-0010
F009 E16-01
F010 1995
F012 21
F013 E18-01
F014 E05-02
F028 A03-03
F029 A03-03
EOR
F001 40
F002 12
F003 13-02-2003
F004 IUC4
F008 E06-0010
F012 21
F013 E18-01
F014 E05-02
EOB
C
B501 TO_ACUTE_ORAL_TAB
F001 40
F002 1
F003 19-11-2002
F004 IUC4
F017 A36-002
F018 1
F007 A01-03: Unrefined base oil Sample API 84-01 [CAS 64741-50-0]  See section
*    1.1.1.
F008 T01-03
F009 T02-24
F011 1986
F012 A02-04
F014 5000
F015 T04-01
F016 A03-03
F019 T24-03
F020 5
F021 T52-003: Non - administered undiluted
F022 T23-42
EOR
F001 40
F002 2
F003 31-12-2002
F004 IUC4
F017 A36-002
F018 2
F007 A01-03: Highly refined Base oil Sample API 83-12 [CAS64742-53-6] See
*    section 1.1.1.
F008 T01-03
F009 T02-24
F011 1986
F012 A02-04
F014 5000
F015 T04-01
F016 A03-03
F019 T24-03
F020 5
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F021 T52-003: Non - administered undiluted
F022 T23-42
EOR
F001 40
F002 3
F003 13-02-2003
F004 IUC4
F018 3
F007 A01-03: Various Base oils
F008 T01-03
F009 T02-24
EOB
C
B502 TO_ACUTE_INHAL_TAB
F001 40
F002 1
F003 31-12-2002
F004 IUC4
F019 A36-002
F020 1
F007 A01-03: Highly refined Base oil Sample API 83-12 [CAS64742-53-6] See
*    section 1.1.1.
F008 T05-03
F009 T02-24
F011 1987
F012 A02-03
F013 2.18
F015 T07-01
F016 4
F017 T08-01
F018 A03-03
F021 T24-03
F022 5
F023 T52-003: Air
F024 T23-42
EOR
F001 40
F002 2
F003 11-09-2010
F004 IUC4
F020 2
F007 A01-03: Various Base oils
F008 T05-03
F009 T02-24
EOB
C
B503 TO_ACUTE_DERMAL_TAB
F001 40
F002 1
F003 19-11-2002
F004 IUC4
F017 A36-002
F018 1
F007 A01-03: Unrefined base oil Sample API 84-01 [CAS 64741-50-0]  See section
*    1.1.1.
F008 T01-03
F009 T02-23
```

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F011 1986
F012 A02-04
F014 2000
F015 T04-01
F016 A03-03
F019 T24-03
F020 4
F021 T52-003: None applied undiluted
F022 T23-31
EOR
F001 40
F002 2
F003 31-12-2002
F004 IUC4
F017 A36-002
F018 2
F007 A01-03: Highly refined Base oil Sample API 83-12 [CAS64742-53-6] See
*    section 1.1.1.
F008 T01-03
F009 T02-23
F011 1986
F012 A02-04
F014 2000
F015 T04-01
F016 A03-03
F019 T24-03
F020 2
F021 T52-003: None - applied undiluted
F022 T23-31
EOR
F001 40
F002 3
F003 13-02-2003
F004 IUC4
F018 3
F007 A01-03: Various Base oils
F008 T01-03
F009 T02-23
EOB
C
B505 TO_SKIN_IRRITATION_TAB
F001 40
F002 1
F003 31-12-2002
F004 IUC4
F014 A36-002
F015 1
F007 A01-03: Unrefined base oil Sample API 84-01 [CAS 64741-50-0]  See section
*    1.1.1.
F008 T02-23
F009 T14-02
F010 1986
F012 T46-05
F013 A03-03
F017 T49-001
F018 T50-001
F019 24
```

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F020 T55-001
F021 6
F022 4.3
F023 T52-003: None - undiluted
EOR
F001 40
F002 2
F003 31-12-2002
F004 IUC4
F014 A36-002
F015 2
F007 A01-03: Highly refined Base oil Sample API 83-12 [CAS64742-53-6] See
*    section 1.1.1.
F008 T02-23
F009 T14-02
F010 1986
F012 T46-05
F013 A03-03
F017 T49-001
F018 T50-001
F019 24
F020 T55-001
F021 6
F022 5.4
F023 T52-003: None - undiluted
EOR
F001 40
F002 3
F003 13-02-2003
F004 IUC4
F015 3
F007 A01-03: Various base oils
F008 T02-23
F017 T49-001
F019 24
F020 T55-001
EOB
C
B506 TO_EYE_IRRITATION_TAB
F001 40
F002 1
F003 19-11-2002
F004 IUC4
F014 A36-002
F015 1
F007 A01-03: Unrefined base oil Sample API 84-01 [CAS 64741-50-0]  See section
*    1.1.1.
F008 T02-23
F009 T16-02
F010 1986
F013 A03-03
F017 T49-001
F018 .1
F019 T56-001
F022 9
EOR
F001 40
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```
F002 2
F003 31-12-2002
F004 IUC4
F014 A36-002
F015 2
F007 A01-03: Highly refined Base oil Sample API 83-12 [CAS64742-53-6] See
*    section 1.1.1.
F008 T02-23
F009 T16-02
F010 1986
F013 A03-03
F017 T49-001
F018 .1
F019 T56-001
F022 9
EOR
F001 40
F002 3
F003 13-02-2003
F004 IUC4
F015 3
F007 A01-03: Various base oils
F008 T02-23
F017 T49-001
F018 .1
F019 T56-001
EOB
C
B507 TO_SENSITIZATION_TAB
F001 40
F002 1
F003 19-11-2002
F004 IUC4
F015 A36-002
F016 1
F007 A01-03: Unrefined base other TS: Unrefined base oil Sample API 84-01 [CAS
*    64741-50-0]  See section 1.1.1.
F008 T18-01
F009 T02-10
F010 T20-03
F011 1986
F013 T21-02
F014 A03-03
F017 10
F018 T53-001
F019 25
F020 T49-002
F021 T54-002
F022 T53-002
F023 1
F024 T49-002
F025 T54-002
F030 T52-003: Paraffin oil
EOR
F001 40
F002 2
F003 31-12-2002
```

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F004 IUC4
F015 A36-002
F016 2
F007 A01-03: Highly refined Base oil Sample API 83-12 [CAS64742-53-6] See
*    section 1.1.1.
F008 T18-01
F009 T02-10
F010 T20-03
F011 1986
F013 T21-02
F014 A03-03
F017 10
F018 T53-001
F019 50
F020 T49-002
F021 T54-002
F022 T53-002
F023 1
F024 T49-002
F025 T54-002
F030 T52-003: Paraffin oil
EOR
F001 40
F002 3
F003 13-02-2003
F004 IUC4
F016 3
F007 A01-03: Various base oils
F008 T18-01
F009 T02-10
EOB
C
B508 TO_REPEATED_DOSE_TAB
F001 40
F002 2
F003 31-12-2002
F004 IUC4
F030 A36-002
F031 4
F007 A01-03: Highly refined Base oil Sample API 83-12 [CAS64742-53-6] See
*    section 1.1.1.
F008 T02-23
F009 T23-31
F010 T24-03
F011 T25-01
F012 T26-16
F013 1986
F014 6 hours each day
F015 3 times each week for a total of 12 applications
F017 200, 1000 and 2000 mg/kg
F018 T27-07
F029 A03-03
EOR
F001 40
F002 3
F003 16-09-2010
F004 IUC4
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F030 A36-002
F031 6
F007 A01-03: White oil
F008 T02-24
F009 T23-16
F010 T24-03
F011 T25-09
F012 T26-10
F013 1992
F014 90 days
F015 Continuous in food
F017 0.002, 0.02, 0.2 & 2.0% in the diet
F018 T27-07
F029 A03-03
EOR
F001 40
F002 4
F003 13-02-2003
F004 IUC4
F031 5
F007 A01-03: Various Base oils
F008 T02-23
F011 T25-01
EOR
F001 40
F002 5
F003 19-11-2002
F004 IUC4
F030 A36-002
F031 3
F007 A01-03: Unrefined base oil Sample API 84-01 [CAS 64741-50-0] See section
* 1.1.1.
F008 T02-23
F009 T23-31
F010 T24-03
F011 T25-01
F013 1986
F014 6 hours each day
F015 3 times each week for a total of 12 applications
F017 200, 1000 and 2000 mg/kg
F018 T27-07
F029 A03-03
EOR
F001 40
F002 7
F003 31-12-2002
F004 IUC4
F030 A36-003
F031 2
F007 A01-03: 3 base oils
F008 T02-24
F009 T23-42
F010 T24-03
F011 T25-08
F013 1991
F014 4 weeks
F015 6 hours/day, 5 days/week

F017 50, 220 & 1000 mg/m3
F018 T27-04
F029 A03-02
F032 C07-001
EOR
F001 40
F002 8
F003 12-10-2002
F004 IUC4
F030 A36-005
F031 1
F007 A01-03: Two samples of highly refined, solvent extracted dewaxed
* paraffinic base oil
F008 T02-24
F009 T23-47
F010 T24-03
F011 T25-08
F013 1989
F014 14 days
F015 Six hours per day
F018 T27-07
F019 A02-04
F020 50
F022 T28-07
F029 A03-02
F032 C07-001
EOB
C
B509 TO_GENETIC_IN_VITRO_TAB
F001 40
F002 1
F003 10-02-2003
F004 IUC4
F016 A36-002
F017 1
F007 A01-03: Various base oils
F008 T30-19: Modified Ames Assay
F010 1984
F011 Salmonella typhimurium strain TA98
F012 T32-02
EOR
F001 40
F002 2
F003 12-09-2010
F004 IUC4
F016 A36-005
F017 2
F007 A01-03: Residual base oils
F008 T30-19: Modified Ames Assay
F011 Salmonella typhimurium strain TA98
F012 T32-02
F013 T33-02
F014 A03-02
EOR
F001 40
F002 3
F003 12-09-2010

F004 IUC4
F016 A36-005
F017 3
F008 T30-19: Modified Ames Assay
F011 Salmonella typhimurium strain TA98
F012 T32-02
F013 T33-02
EOB
C
B510 TO_GENETIC_IN_VIVO_TAB
F001 40
F002 1
F003 30-10-2001
F004 IUC31
F018 A36-005
F008 T34-01
F009 T02-24
F010 T23-42
F013 T24-03
F014 T25-03
F015 5 days
F016 Ranged from 500 to 2000 and 500 to 5000 mg/kg
EOB
C
B511 TO_CARCINOGENICITY_TAB
F001 40
F002 2
F003 12-09-2010
F004 IUC4
F021 1
F007 A01-03: Distillate base oils
F008 T02-18
F010 T24-03
F011 T38-01
F014 Up to 84 weeks
F015 once or twice weekly
F017 various
F018 T27-04
EOR
F001 40
F002 4
F003 26-08-2002
F004 IUC4
F020 A36-002
F021 4
F007 A01-03: White oil
F008 T02-24
F009 T23-16
F010 T24-03
F011 T38-10
F012 T39-04
F013 2001
F014 2 years
F015 Daily in the diet
F017 60, 120, 240 and 1200 mg/kg/day
F018 T27-07
F019 A03-03

F022 T33-02
EOR
F001 40
F002 5
F003 12-09-2010
F004 IUC4
F020 A36-003
F008 T02-24
F009 T23-16
F010 T24-03
F011 T38-10
F013 1997
F014 104 weeks
F015 continuous in the feed
F017 2.5 and 5% in the diet
F018 T27-07
F022 T33-02
EOR
F001 40
F002 6
F003 12-09-2010
F004 IUC4
F020 A36-005
F021 2
F007 A01-03: Residual base oils
F008 T02-18
F009 T23-48: CF No. 1
F010 T24-01
F011 T38-01
F013 1991
F014 18 months
F015 Three times weekly
F017 0.1ml/application
F018 T27-07
F019 A03-02
F022 T33-02
EOR
F001 40
F002 7
F003 06-09-2002
F004 IUC4
F020 A36-005
F021 3
F007 A01-03: Canthus 210 a Deasphalted, dewaxed, residual oil
F008 T02-18
F009 T23-07
F010 T24-02
F011 T38-01
F015 3 times weekly
F017 25 µl per application
F018 T27-07
F019 A03-02
F022 T33-02
EOB
C
B512 TO_REPRODUCTION_TAB
F001 40

F002 1
F003 12-09-2010
F004 IUC4
F037 A36-003
F007 A01-03: Chevron 100 neutral (refined) CAS 64742-54-7
F008 T41-02
F009 T02-24
F010 T23-42
F011 T24-03
F012 T25-03
F013 T40-05: OECD Guideline 421, Reproductive/Developmental Toxicity screening
*   test
F014 1995
F015 Daily
F019 1.15 mg/kg
F020 T27-01
F035 A03-03
EOR
F001 40
F002 2
F003 13-02-2003
F004 IUC4
F037 A36-003
F007 A01-03: White oil CAS 8012-95-1
F008 T41-02
F009 T02-24
F010 T23-42
F011 T24-03
F012 T25-03
F036 13 weeks prior to mating
F014 1987
F015 5 times weekly
F016 13 weeks
F017 13 weks
F018 one generation after 13 weeks dosing
F019 5 ml/kg
F020 T27-01
F035 A03-02
F054 1
EOB
C
B513 TO_DEVELOPMENTAL_TAB
F001 40
F002 1
F003 13-02-2003
F004 IUC4
F030 A36-003
F007 A01-03: White oil CAS 8012-95-1
F008 T02-24
F009 T23-42
F010 T24-01
F011 T25-03
F013 1987
F015 Days 6 through 19 of gestation
F016 daily
F029 A03-02
EOB

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C
B019 TO_SPEC_INVEST_TAB
F001 40
F002 1
F003 24-08-2023
F004 IUC4
EOB
C
B514 TO_OTHER_TAB
F001 40
F002 1
F003 30-01-2002
F004 IUC31
F008 A36-003
F009 3
F007 T45-12: Developmental toxicity screen on Heavy vacuum gas oil
EOR
F001 40
F002 2
F003 11-10-2002
F004 IUC4
F009 1
F007 T45-12: Correlation of toxicity with chemical components of refinery
*    streams
EOR
F001 40
F002 3
F003 04-11-2002
F004 IUC4
F008 A36-003
F009 2
F007 T45-12: 90-day study on Heavy vacuum gas oil
EOB
C
B601 TEXT_TAB
F002 40
F010 1.1.1
F004 1
F005 AD
F006 Phys.chem.data.doc
F007 Phys.chem.data.doc
F020 3605
F021 Phys.chem.data
F022 20992
F023 11:2:2003 19:15
F024 doc
EOR
F002 40
F010 1.1.1
F004 1
F005 RE
F006 CONCAWE (1997)
**   Lubricating oil basestocks
**   Product dossier No. 97/108
**   CONCAWE, Brussels
F007 CONCAWE (1997)
**   Lubricating oil basestocks
```

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**   Product dossier No. 97/108
**   CONCAWE, Brussels
F020 3603
EOR
F002 40
F010 1.1.1
F004 1
F005 RM
F006 The group of base oils consists of products that are derived
**   from both distillates and residues of the vacuum
**   distillation process in petroleum refining.
**
**   Base oils consist predominantly of hydrocarbons but may also
**   contain small quantities
F007 The group of base oils consists of products that are derived
**   from both distillates and residues of the vacuum
**   distillation process in petroleum refining.
**
**   Base oils consist predominantly of hydrocarbons but may also
**   contain small quantities of sulfur and nitrogen compounds
**   with traces of a number of metals. The oils contain complex
**   hydrocarbons with variable mixtures of paraffins, naphthenes
**   and aromatics with carbon numbers in the range 15 to 50.
**   Hydrocarbon constituents derived from vacuum distillates
**   boil generally in the range 300 to 600 °C, whereas those
**   derived from residual oils may boil up to 800 °C.
**
**   Unrefined vacuum distillates contain polycyclic aromatic
**   compounds (PACs) which are removed during any subsequent
**   refining process.  The more severe the refining, the lower
**   the PAC content will be of the refined base oil.
**
**   Physical chemical data for a range of base oils have been
**   summarized by CONCAWE and these are tabulated in the
**   attached document.
**
**   For most of the mammalian toxicology endpoints, information
**   has been used that was derived by the American Petroleum
**   Institute on a wide range of base oils. For simplicity, this
**   robust summary contains detailed information on an API
**   sample of an unrefined distillate (high PAC) and an API
**   sample of a highly refined distillate (low PAC).  If data
**   was available on other samples, it has either been
**   summarized in tabular form in the relevant sections of this
**   summary or discussed in detail when appropriate.
**
**   The API sample of highly refined base oil for which data
**   have
**   been selected is one with a low average molecular weight
**   since this is likely to represent the worst case from a
**   toxicological perspective.
**
**   The physico-chemical characteristics of the two samples are
**   as follows:
**
**                Method      Unrefined   Highly
      oil         refined
```

```
**                                  oil
**
**   API sample No.                 84-01       83-12
**   CAS No.                        64741-50-0  64742-53-6
**   API Gravity @60°   D287   31.9       25.9
**   Density @15°C            D287  0.8651            0.8981
**   Molecular wt. (gm/mol)   D2224 300         260
**   Refractive index
**    (RI units @20 °C) 1.4815            1.4910
**   Total Sulfur (wt. %)     D3120 0.38        0.04
**   Total Nitrogen (ppm/wt)  Chemil      210         38
**   Total oxygen (wt.%)      NAA   0.038       0.077
**   Total Chloride (ppm/wt) coulom 11          2
**   Viscosity (cSt @ 40°C)   D445  14.07       0.44
**   Viscosity (cSt @ 100°C)  D445  2.79        2.14
**   Pour point (°F)          D93   +60         <-20
**   Carbon residue (wt. %)   D524  0.15        0.14
**   Distillation       D1160
**          IBP (°F)    595         450
**          FBP (°F)    810         785
**
**   Hydrocarbon type analysis
**   Nonaromatics (wt. %)     D2549 79.1        67.3
**   Aromatics (wt. %)  D2549 20.9        31.9
**                TOTAL 100         100
**
**
**
**   Some oils are destined for food use or pharmaceutical
**   applications and for these the refining process that they
**   undergo is particularly severe to ensure that aromatic
**   materials have been removed and that the resulting oil is
**   colorless.  Such oils are known as white oils.  Unlike the
**   other base oils in which oral intake is unintentional, the
**   white oils are intended for uses in which an oral intake is
**   likely. For these materials, oral studies are available and,
**   where appropriate, are included in this Robust Summary .
**
**   Several individual companies have generated data on
**   environmental effects and ecotoxicity. The relevant CAS
**   descriptions of the materials that have been tested are
**   included in the relevant sections of this robust summary.
F020 3604
EOR
F002 40
F010 1.13
F004 1
F005 RE
F006 IARC (1984)
**   IARC Monographs on the evaluation of the carcinogenic risk
**   of chemicals to humans, Volume 33: Polynuclear aromatic
**   hydrocarbons, part 2, carbon blacks, mineral oils (lubricant
**   base oils and derived products) and some nitroarenes
F007 IARC (1984)
**   IARC Monographs on the evaluation of the carcinogenic risk
**   of chemicals to humans, Volume 33: Polynuclear aromatic
**   hydrocarbons, part 2, carbon blacks, mineral oils (lubricant
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**   base oils and derived products) and some nitroarenes.
**   International Agency for Research on Cancer, Lyon.
F020 3606
EOR
F002 40
F010 1.13
F004 3
F005 RE
F006 Bingham, E. Trosset, R. P., Warshawsky, D. (1980)
**   Carcinogenic potential of petroleum hydrocarbons, a critical
**   review of the literature.
**   J. Environmental Pathology and Toxicology, Vol 3, pp
**   483-563.
F007 Bingham, E. Trosset, R. P., Warshawsky, D. (1980)
**   Carcinogenic potential of petroleum hydrocarbons, a critical
**   review of the literature.
**   J. Environmental Pathology and Toxicology, Vol 3, pp
**   483-563.
F020 3607
EOR
F002 40
F010 1.13
F004 4
F005 RE
F006 CONCAWE (1994)
**   The use of the dimethyl sulphoxide (DMSO) extract by the IP
**   346 method as an indicator of the carcinogenicity of
**   lubricant base oils and distillate aromatic extracts.
**   CONCAWE Report No. 94/51
**   CONCAWE, Brussels.
F007 CONCAWE (1994)
**   The use of the dimethyl sulphoxide (DMSO) extract by the IP
**   346 method as an indicator of the carcinogenicity of
**   lubricant base oils and distillate aromatic extracts.
**   CONCAWE Report No. 94/51
**   CONCAWE, Brussels.
F020 3608
EOR
F002 40
F010 1.13
F004 4
F005 RE
F006 EU (1994)
**   Commission Directive 94/69/EC of 19 December 1994 adapting
**   to technical progress for the 21st time Council Directive
**   67/548/EEC on the approximation of the laws, regulations and
**   administrative provisions relating to the classifica
F007 EU (1994)
**   Commission Directive 94/69/EC of 19 December 1994 adapting
**   to technical progress for the 21st time Council Directive
**   67/548/EEC on the approximation of the laws, regulations and
**   administrative provisions relating to the classification,
**   packaging and labelling of dangerous substances.
**   Official Journal of the European Communities No L381,
**   31.12.1994
F020 3609
EOR
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F002 40
F010 1.13
F004 4
F005 RM
F006 The DMSO method was adopted subsequently in the EU to
** distinguish between carcinogenic and non-carcinogenic oils
** for classification and labeling purposes.
F007 The DMSO method was adopted subsequently in the EU to
** distinguish between carcinogenic and non-carcinogenic oils
** for classification and labeling purposes.
F020 3610
EOR
F002 40
F010 1.13
F004 5
F005 RE
F006 JECFA (1996)
** Toxicological evaluation of certain food additives and
** contaminants. Prepared by the 44th meting of the Joint
** FAO/WHO Expert Committee on Food Additives (JECFA).
** WHO Food Additives Series 35. Geneva.
F007 JECFA (1996)
** Toxicological evaluation of certain food additives and
** contaminants. Prepared by the 44th meting of the Joint
** FAO/WHO Expert Committee on Food Additives (JECFA).
** WHO Food Additives Series 35. Geneva.
F020 3611
EOR
F002 40
F010 1.13
F004 5
F005 RE
F006 SCF (1995)
** Opinion on mineral and synthetic hydrocarbons (expressed on
** 22 September 1995)
** CS/ADD/MsAd/132-Final, Brussels, European Commision
F007 SCF (1995)
** Opinion on mineral and synthetic hydrocarbons (expressed on
** 22 September 1995)
** CS/ADD/MsAd/132-Final, Brussels, European Commision
F020 3612
EOR
F002 40
F010 1.13
F004 6
F005 RE
F006 WHO (1982)
** Selected Petroleum Products
** Environ. Health Criteria Document No. 20.
** World Health Organization, Geneva
F007 WHO (1982)
** Selected Petroleum Products
** Environ. Health Criteria Document No. 20.
** World Health Organization, Geneva
F020 3613
EOR
F002 40

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F010 1.8.1
F004 1
F005 RE
F006 ACGIH (1998)
**   1998 TLVs and BEIs Threshold limit values for chemical
**   substances and physical agents.
F007 ACGIH (1998)
**   1998 TLVs and BEIs Threshold limit values for chemical
**   substances and physical agents.
F008 IUC4
F009 11-09-2010
F020 3614
EOR
F002 40
F010 1.8.1
F004 1
F005 RM
F006 A TWA TLV of 0.005 mg/m3 is proposed for the sum total of 15
**   polynuclear aromatic hydrocarbons (PAHs) listed as
**   carcinogens by the U.S. National Toxicology Program (NTP).
F007 A TWA TLV of 0.005 mg/m3 is proposed for the sum total of 15
**   polynuclear aromatic hydrocarbons (PAHs) listed as
**   carcinogens by the U.S. National Toxicology Program (NTP).
F008 IUC4
F020 3615
EOR
F002 40
F010 2.1
F004 1
F005 RE
F006 American Society for Testing and Materials (ASTM). (1999)
**   Standard Test Method for Pour Point of Petroleum Oils.
**   ASTM D97, Volume 05.01, ASTM, West Conshohocken, PA.
F007 American Society for Testing and Materials (ASTM). (1999)
**   Standard Test Method for Pour Point of Petroleum Oils.
**   ASTM D97, Volume 05.01, ASTM, West Conshohocken, PA.
F008 IUC4
F020 3616
EOR
F002 40
F010 2.1
F004 1
F005 RE
F006 American Society for Testing and Materials (ASTM). (2002)
**   Standard Test Method for Pour Point of Petroleum Products
**   (Rotational Method).
**   ASTM D5985-02, Volume 05.01, ASTM, West Conshohocken, PA.
F007 American Society for Testing and Materials (ASTM). (2002)
**   Standard Test Method for Pour Point of Petroleum Products
**   (Rotational Method).
**   ASTM D5985-02, Volume 05.01, ASTM, West Conshohocken, PA.
F008 IUC4
F020 3617
EOR
F002 40
F010 2.1
F004 1
```

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F005 RE
F006 CONCAWE (1997)
**   Lubricating oil basestocks
**   Product dossier No. 97/108
**   CONCAWE, Brussels
F007 CONCAWE (1997)
**   Lubricating oil basestocks
**   Product dossier No. 97/108
**   CONCAWE, Brussels
F008 IUC4
F020 3618
EOR
F002 40
F010 2.1
F004 1
F005 RL
F006 Results of standard method testing was reported in a
**   reliable review dossier.
F007 Results of standard method testing was reported in a
**   reliable review dossier.
F008 IUC4
F020 3619
EOR
F002 40
F010 2.1
F004 1
F005 RM
F006 By definition, melting point is the temperature at which a
**   solid becomes a liquid at normal atmospheric pressure.  For
**   complex mixtures like petroleum products, melting point may
**   be characterized by a range of temperatures reflecting the
**   me
F007 By definition, melting point is the temperature at which a
**   solid becomes a liquid at normal atmospheric pressure.  For
**   complex mixtures like petroleum products, melting point may
**   be characterized by a range of temperatures reflecting the
**   melting points of the individual components. To better
**   describe phase or flow characteristics of petroleum
**   products, the pour point is routinely used.  The pour point
**   is the lowest temperature at which movement of the test
**   specimen is observed under prescribed conditions of the test
**   (ASTM 2002). In addition, the pour point methodology defines
**   a "no-flow" point, defined as the temperature of the test
**   specimen at which a wax crystal structure or viscosity
**   increase, or both, impedes movement of the surface of the
**   test specimen under the conditions of the test (ASTM 2002).
**   Because not all petroleum products contain wax in their
**   composition, the pour point determination encompasses either
**   change in physical state (i.e., crystal formation) and/or
**   viscosity property.
F008 IUC4
F020 3620
EOR
F002 40
F010 2.1
F004 1
F005 RS
```

F006 See following Table and Remarks Section
**
**   Distillate Oils   Pour Point, °C
**   Solvent de-waxed, light paraffinic
**   (CAS No. 64742-56-9)   -18
**
**   Solvent de-waxed, heavy paraffinic
**   (CAS No. 64742-65-0)   -12
**
**   Hydrotreated, light paraffinic
F007 See following Table and Remarks Section
**
**   Distillate Oils   Pour Point, °C
**   Solvent de-waxed, light paraffinic
**   (CAS No. 64742-56-9)   -18
**
**   Solvent de-waxed, heavy paraffinic
**   (CAS No. 64742-65-0)   -12
**
**   Hydrotreated, light paraffinic
**   (CAS No. 64742-55-8)   -18
**
**   Hydrotreated, heavy paraffinic
**   (CAS No. 64742-54-7)   -9
**
**   Hydrotreated, light naphthenic
**   (CAS No. 64742-53-6)   -60
**
**   Hydrotreated, heavy naphthenic
**   (CAS No. 64742-52-5)   -24
**
**   White mineral oil
**   (CAS No. 8042-47-5)   -15
**
**   Residual Oils
**   Solvent de-waxed
**   (CAS No. 64742-62-7)   -6
**
F008 IUC4
F020 3621
EOR
F002 40
F010 2.2
F004 1
F005 RE
F006 CONCAWE (1997)
**   Lubricating oil basestocks
**   Product dossier No. 97/108
**   CONCAWE, Brussels
F007 CONCAWE (1997)
**   Lubricating oil basestocks
**   Product dossier No. 97/108
**   CONCAWE, Brussels
F008 IUC4
F020 3622
EOR
F002 40

F010 2.2
F004 1
F005 RE
F006 US EPA. (2000)
** EPI (Estimation Programs Interface for Windows) Suite,
** V3.10, Subroutine MPBPWIN V1.40.
** U.S. Environmental Protection Agency, Office of Pollution
** Prevention and Toxics, Washington, DC.
F007 US EPA. (2000)
** EPI (Estimation Programs Interface for Windows) Suite,
** V3.10, Subroutine MPBPWIN V1.40.
** U.S. Environmental Protection Agency, Office of Pollution
** Prevention and Toxics, Washington, DC.
F008 IUC4
F020 3623
EOR
F002 40
F010 2.2
F004 1
F005 RM
F006 The substances covered in lubricating base oils are complex
** and variable mixtures of paraffins, naphthenes
** (cycloparaffins), and aromatics having carbon numbers
** ranging from about 15 to 50. Because they are mixtures,
** lubricating base oils
F007 The substances covered in lubricating base oils are complex
** and variable mixtures of paraffins, naphthenes
** (cycloparaffins), and aromatics having carbon numbers
** ranging from about 15 to 50. Because they are mixtures,
** lubricating base oils do not have a single numerical value
** for boiling point, but rather a boiling range that reflects
** the individual components. Base oils are produced from
** vaccum distillation of the residue obtained after the
** atmospheric distillation of crude oil. The vacuum
** distillates and the vacuum residues together form the
** general group of unrefined or mildly refined base oil.
** Additional treatments or refinements such as solvent
** extraction, dewaxing, and hydrogenation, are employed to
** produce oils with desirable properties. The ranges of
** components modeled using MPBPWIN V1.40 are given in the
** table above. Those values are consistent with information
** provided by CONCAWE (1997) that indicated component
** hydrocarbons of oils produced from vacuum distillation have
** boiling points ranging from 300 to 600°C whereas those
** produced from vacuum residues contain components with
** boiling points as high as 800°C (CONCAWE 1997).
F008 IUC4
F020 3624
EOR
F002 40
F010 2.2
F004 1
F005 RS
F006 See Remarks Section
** Calculated Boiling Point Ranges, °C:
** C15 to C50 Paraffinic: 250 to 682
** C15 to C50 Naphthenic: 282 to 683

```
**   C15 TO C50 Aromatic:     312 to 788
F007 See Remarks Section
**   Calculated Boiling Point Ranges, °C:
**   C15 to C50 Paraffinic:   250 to 682
**   C15 to C50 Naphthenic:   282 to 683
**   C15 TO C50 Aromatic:     312 to 788
F008 IUC4
F020 3625
EOR
F002 40
F010 2.4
F004 1
F005 RE
F006 Hazleton UK for Shell Research Ltd. (1991)
**   Determination of Vapour Pressure.
**   Report No. 6736-579/70.
F007 Hazleton UK for Shell Research Ltd. (1991)
**   Determination of Vapour Pressure.
**   Report No. 6736-579/70.
F008 IUC4
F020 3626
EOR
F002 40
F010 2.4
F004 1
F005 RS
F006 Three runs on the sample were conducted. There was initially
**   substantial reduction (equivalent to 3°C temperature change)
**   of estimated VP on prolonged pumping after Run 1 but this
**   was reduced to the equivalent of 0.65°C change between Runs
F007 Three runs on the sample were conducted. There was initially
**   substantial reduction (equivalent to 3°C temperature change)
**   of estimated VP on prolonged pumping after Run 1 but this
**   was reduced to the equivalent of 0.65°C change between Runs
**   2 and 3. The latter runs provided values at room temperature
**   of 1.882 and 1.563 x 10-4 Pascals, yielding a mean value of
**   Vp(298.15K) = 1.723 x 10-4 Pascals. The condensation rates
**   onto the pan observed in Run 3 increased with temperature
**   more rapidly than the mass difference indicating an
**   increasing efficiency of condensation and thus precluding
**   the use of the condensation data to produce a satisfactory
**   VP relation. The final values of rate of condensation were
**   however equivalent in pressure regime to the mass
**   differences assuming a rough equality between the numerical
**   magnitudes of temperature and molar mass.
F008 IUC4
F020 3627
EOR
F002 40
F010 2.4
F004 1
F005 TC
F006 The vapor pressure (VP) was determined using a VP balance
**   based on a CI Electronics micro-balance with a sensitivity
**   of approximately 0.1 mg. Sample temperature was controlled
**   electronically (±1°C) over the range from ambient to 250°C.
**   Mass
```

F007 The vapor pressure (VP) was determined using a VP balance
** based on a CI Electronics micro-balance with a sensitivity
** of approximately 0.1 mg. Sample temperature was controlled
** electronically (±1°C) over the range from ambient to 250°C.
** Mass readings and temperature were recorded directly onto a
** 2-channel chart recorder. The VP balance was designed such
** that on opening the slide across the orifice in the
** temperature controlled evaporation furnace, the escaping
** vapor jet was directed at the scale pan. VP was determined
** directly from the pressure on the scale pan by measuring the
** difference of mass readings when the slide across the
** orifice was open and closed. When condensation occurred onto
** the pan the VP can be calculated from the condensation rate
** if the molar mass is known. VP of the sample was measured at
** several temperatures to yield VP curves for subsequent
** extrapolation to give 298.15K values. Slope and intercept of
** VP curve were estimated by an unweighted least squares
** statistical treatment of the data and errors are ± standard
** deviation of the respective quantity. Maximum and minimum
** values of VP at 298.15K were calculated directly from the VP
** relationship using the ranges of errors in slope and
** intercept respectively. The quoted errors in VP at 298.15K
** were then calculated directly by extrapolation from these
** values.
F008 IUC4
F020 3628
EOR
F002 40
F010 3.1.1
F004 1
F005 RE
F006 Atkinson, R. (1990).
** Gas-phase tropospheric chemistry of organic compounds: a
** review
** Atmos. Environ., Vol. 24A, pp. 1-41
F007 Atkinson, R. (1990).
** Gas-phase tropospheric chemistry of organic compounds: a
** review
** Atmos. Environ., Vol. 24A, pp. 1-41
F008 IUC4
F020 3629
EOR
F002 40
F010 3.1.1
F004 1
F005 RE
F006 CONCAWE (2001).
** Environmental Classification Of Petroleum Substances
** -Summary Data And Rationale
** Report 01/54,
F007 CONCAWE (2001).
** Environmental Classification Of Petroleum Substances
** -Summary Data And Rationale
** Report 01/54,
F008 IUC4
F009 11-09-2010
F020 3630

EOR
F002 40
F010 3.1.1
F004 1
F005 RE
F006 U.S. EPA. (2001).
** EPI (Estimation Programs Interface) Suite, V3.10. U.S.
** Environmental Protection Agency, Office of Pollution
** Prevention and Toxics, Washington, DC.
F007 U.S. EPA. (2001).
** EPI (Estimation Programs Interface) Suite, V3.10. U.S.
** Environmental Protection Agency, Office of Pollution
** Prevention and Toxics, Washington, DC.
F008 IUC4
F020 3631
EOR
F002 40
F010 3.1.1
F004 1
F005 RL
F006 The predicted endpoint was determined using a validated
** computer model.
F007 The predicted endpoint was determined using a validated
** computer model.
F008 IUC4
F020 3632
EOR
F002 40
F010 3.1.1
F004 1
F005 RM
F006 AOPWIN V1.90 calculates atmospheric oxidation half lives of
** hydrocarbons in contact with hydroxyl radicals in the
** troposphere, under the influence of sunlight. Atmospheric
** oxidation rates were calculated for the lowest molecular
** weight cons
F007 AOPWIN V1.90 calculates atmospheric oxidation half lives of
** hydrocarbons in contact with hydroxyl radicals in the
** troposphere, under the influence of sunlight. Atmospheric
** oxidation rates were calculated for the lowest molecular
** weight constituents, i.e., C15 hydrocarbon components.
** Although the low vapor pressures of these base oils
** indicate that volatilization will not be a very significant
** fate process, oxidation half-lives indicate this may be a
** moderate removal process if these substances were introduced
** to the atmosphere by adsorption to particulate matter via
** atmospheric emissions. The half-lives for degradation of
** these hydrocarbons by reaction with hydroxyl radicals, in
** the troposphere, under the influence of sunlight, will all
** be less than one day, by extrapolation from the data quoted
** by Atkinson (1990).
**
** In general, most products in the base oil category do not
** contain component molecules that will undergo direct
** photolysis. Saturated hydrocarbons (paraffins and
** naphthenics), and single ring aromatics, which constitute
** the majority of these components, do not absorb appreciable

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**   light energy above 290 nm. Therefore, direct photolysis will
**   not contribute to a measurable degradative removal of
**   chemical components in this category from the environment.
F008 IUC4
F020 3633
EOR
F002 40
F010 3.1.1
F004 1
F005 RS
F006 Indirect photolysis at 25 °C
**   Concentration of sensitizer: 1.50 x 10 6 OH radicals/cm3
**   Rate constant: 18.1757 x 10 -12 cm3/mol-sec
**   Half-life: 0.053 - 0.66 days for C15 hydrocarbon
**   constituents
F007 Indirect photolysis at 25 °C
**   Concentration of sensitizer: 1.50 x 10 6 OH radicals/cm3
**   Rate constant: 18.1757 x 10 -12 cm3/mol-sec
**   Half-life: 0.053 - 0.66 days for C15 hydrocarbon
**   constituents
F008 IUC4
F020 3634
EOR
F002 40
F010 3.1.2
F004 1
F005 CL
F006 Hydrolysis of an organic chemical is the transformation
**   process in which a water molecule or hydroxide ion reacts to
**   form a new carbon-oxygen bond. Chemicals that have a
**   potential to hydrolyze include alkylhalides, amides,
**   carbamates, carbo
F007 Hydrolysis of an organic chemical is the transformation
**   process in which a water molecule or hydroxide ion reacts to
**   form a new carbon-oxygen bond. Chemicals that have a
**   potential to hydrolyze include alkylhalides, amides,
**   carbamates, carboxylic acid esters and lactones, epoxides,
**   phosphate esters, and sulfonic acid esters. The chemical
**   components that comprise the base oil category are
**   hydrocarbons, which are not included in these chemical
**   groups, and they are not subject to hydrolysis reactions
**   with water.
F008 IUC4
F020 3635
EOR
F002 40
F010 3.1.2
F004 1
F005 RE
F006 Harris, J.C. (1982).
**   Rate of Hydrolysis. In Handbook of Chemical Property
**   Estimation Methods. p. 7-6.
**   W. J.  Lyman, W.F. Reehl and D.H. Rosenblatt, eds.
**   McGraw-Hill Book Company, New York, NY, USA.
F007 Harris, J.C. (1982).
**   Rate of Hydrolysis. In Handbook of Chemical Property
**   Estimation Methods. p. 7-6.
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**   W. J.  Lyman, W.F. Reehl and D.H. Rosenblatt, eds.
**   McGraw-Hill Book Company, New York, NY, USA.
F008 IUC4
F020 3636
EOR
F002 40
F010 3.1.2
F004 1
F005 RS
F006 Measured value:          N/A
**   Degradation %:           N/A
**   Half-life:         N/A
**   Breakdown products:      N/A
F007 Measured value:          N/A
**   Degradation %:           N/A
**   Half-life:         N/A
**   Breakdown products:      N/A
F008 IUC4
F020 3637
EOR
F002 40
F010 3.3.1
F004 2
F005 AD
F006 Distribution.doc
F007 Distribution.doc
F008 IUC4
F020 3638
F021 AD2114
F022 36352
F023 7:2:2003 11:4
F024 doc
EOR
F002 40
F010 3.3.1
F004 2
F005 AD
F006 fugacity graph.doc
F007 fugacity graph.doc
F008 IUC4
F020 3639
F021 AD2115
F022 91136
F023 7:2:2003 11:4
F024 doc
EOR
F002 40
F010 3.3.1
F004 2
F005 CL
F006 This complex petroleum mixture is expected to partition
**   primarily to soil and/or sediment.
F007 This complex petroleum mixture is expected to partition
**   primarily to soil and/or sediment.
F008 IUC4
F020 3640
EOR
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F002 40
F010 3.3.1
F004 2
F005 RE
F006 CONCAWE (2001).
** Environmental Classification Of Petroleum Substances
** -Summary Data And Rationale
** Report 01/54,
F007 CONCAWE (2001).
** Environmental Classification Of Petroleum Substances
** -Summary Data And Rationale
** Report 01/54,
F008 IUC4
F020 3641
EOR
F002 40
F010 3.3.1
F004 2
F005 RE
F006 Trent University. (1999)
** Level 1 Fugacity-Based Environmental Equilibrium
** Partitioning Model, V2.11.
** Environmental Modelling Centre, Trent University, Canada.
F007 Trent University. (1999)
** Level 1 Fugacity-Based Environmental Equilibrium
** Partitioning Model, V2.11.
** Environmental Modelling Centre, Trent University, Canada.
F008 IUC4
F020 3642
EOR
F002 40
F010 3.3.1
F004 2
F005 RL
F006 The predicted endpoint was determined using a validated
** computer model.
F007 The predicted endpoint was determined using a validated
** computer model.
F008 IUC4
F020 3643
EOR
F002 40
F010 3.3.1
F004 2
F005 RM
F006 Model based on chemical fugacity. Multimedia distribution
** was calculated for C15 hydrocarbons, the lowest molecular
** components found in base oils. Larger molecular weight
** components are expected to exhibit greater partitioning
** behavior to t
F007 Model based on chemical fugacity. Multimedia distribution
** was calculated for C15 hydrocarbons, the lowest molecular
** components found in base oils. Larger molecular weight
** components are expected to exhibit greater partitioning
** behavior to terrestrial media. Mobility in the aquatic and
** atmospheric environment is low due to low water solubility
** and low vapor pressure. These components will partition

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**   rapidly to the terrestrial compartment, where the main fate
**   process is expected to be slow biodegradation of base oil
**   components in soil and sediment.
**
**   A summary of the EQC modeling of the distribution and
**   transport between environmental compartments for selected
**   hydrocarbon compounds in lubricant base oils is presented in
**   the attached table and graph. The compounds selected for
**   modeling represent various C15 compounds in base oils (e.g.,
**   linear and branched paraffins, naphthenes and aromatic
**   hydrocarbons).
F008 IUC4
F020 3644
EOR
F002 40
F010 3.3.1
F004 2
F005 RS
F006 Medium             % distribution
**   Air:               0 to 94
**   Soil:              6 to 97
**   Water:                   0.88 to <0.0001
**   Sediment           <0.1 to 2
**   Suspended Sediment       <0.02 to 0.004
F007 Medium             % distribution
**   Air:               0 to 94
**   Soil:              6 to 97
**   Water:                   0.88 to <0.0001
**   Sediment           <0.1 to 2
**   Suspended Sediment       <0.02 to 0.004
F008 IUC4
F020 3645
EOR
F002 40
F010 3.5
F004 1
F005 RE
F006 Shell Research Ltd. (1986)
**   Base Oils: An Assessment of Ready Biodegradability. Report
**   No. SBGR.86.137.
F007 Shell Research Ltd. (1986)
**   Base Oils: An Assessment of Ready Biodegradability. Report
**   No. SBGR.86.137.
F008 IUC4
F020 3646
EOR
F002 40
F010 3.5
F004 1
F005 RL
F006 The study report lacked an extensive description of
**   experimental procedures but instead referenced procedures
**   detailed in a laboratory SOP.
F007 The study report lacked an extensive description of
**   experimental procedures but instead referenced procedures
**   detailed in a laboratory SOP.
F008 IUC4
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F020 3647
EOR
F002 40
F010 3.5
F004 1
F005 RS
F006 The test substance was partially degraded to 20-26% of the
** theoretical CO2 in 28 days. Degradation commenced after a
** lag period of 2 days. Biodegradation curve showed that
** degradation had virtually stopped by day 28. Test substance
** was th
F007 The test substance was partially degraded to 20-26% of the
** theoretical CO2 in 28 days. Degradation commenced after a
** lag period of 2 days. Biodegradation curve showed that
** degradation had virtually stopped by day 28. Test substance
** was therefore inherently biodegradable since it achieved
** >20% biodegradability based upon CO2 evolution.
** % Degradation Mean
** Sample (day 28) % Degraded
** Test substance 26, 20 23
** Na Benzoate 86, 92 89
F008 IUC4
F020 3648
EOR
F002 40
F010 3.5
F004 1
F005 TC
F006 The test substance was added to test medium from a stock
** solution containing 2.4 g/l emulsified in Dobane PT
** sulphonate (2 mg/l), a non-biodegradable detergent. The
** final test concentration of the base oil was 20 mg/l. The
** test medium was d
F007 The test substance was added to test medium from a stock
** solution containing 2.4 g/l emulsified in Dobane PT
** sulphonate (2 mg/l), a non-biodegradable detergent. The
** final test concentration of the base oil was 20 mg/l. The
** test medium was dispensed into Sturm vessels, inoculated and
** aerated with 60 ml/min of CO2-free air and incubated at 20 ±
** 1°C. Biodegradation was determined on days 1, 2, 5, 9,
** 14, 20, and 28 by titrating the total CO2 released. The
** medium was acidified on day 27 to release the total CO2 by
** day 28. Test substance, control blank, and sodium benzoate
** control (20 mg/l) were tested in duplicates. The empirical
** formula used was CnH2n+1 which yielded a theoretical CO2
** evolution of 3.14 g CO2 per g of test substance.
F008 IUC4
F020 3649
EOR
F002 40
F010 3.5
F004 3
F005 RE
F006 Exxon Biomedical Sciences, Inc. (1995)
** Ready Biodegradability, Manometric Respirometry.
** Study #198194A.
F007 Exxon Biomedical Sciences, Inc. (1995)

** Ready Biodegradability, Manometric Respirometry.
** Study #198194A.
F008 IUC4
F020 3650
EOR
F002 40
F010 3.5
F004 3
F005 RS
F006 By day 28, 31% degradation of the test material was observed
** and indicated that the test material was inherently
** biodegradable.
** By day 5, >60% biodegradation of positive control was
** observed, which meets the guideline requirement. No
** excu
F007 By day 28, 31% degradation of the test material was observed
** and indicated that the test material was inherently
** biodegradable.
** By day 5, >60% biodegradation of positive control was
** observed, which meets the guideline requirement. No
** excursions from the protocol were noted.
** Biodegradation was based on net oxygen consumption and the
** theoretical oxygen demand of the test material as calculated
** using results of an elemental analysis of the test
** material.
** % Degradation* Mean % Degradation
** Sample (day 28) (day 28)
** HHP 32.93, 27.2,33.27 31.13
** Na Benzoate 82.04; 72.88 77.46
**
** * replicate data
F008 IUC4
F020 3651
EOR
F002 40
F010 3.5
F004 3
F005 TC
F006 Fresh activated sludge was obtained one day prior to test
** initiation, and homogenized in a blender for two minutes.
** After allowing the sample to settle for approximately 30
** minutes, the homogenated supernatant was decanted, avoiding
** carry-o
F007 Fresh activated sludge was obtained one day prior to test
** initiation, and homogenized in a blender for two minutes.
** After allowing the sample to settle for approximately 30
** minutes, the homogenated supernatant was decanted, avoiding
** carry-over of solids. Microbial activity of an aliquot of
** the filtered supernatant was 1E6 CFU/ml which was
** determined
** using microbial agar dip slides. Activated sludge
** supernatant was added to the test medium at 10 ml/l and the
** inoculated medium was continuously aerated with CO2-free air
** until the next day when the test systems were prepared.
** Test medium consisted of glass distilled water and mineral
** salts (phosphate buffer, ferric chloride, magnesium sulfate,
** calcium chloride). Test vessels were 1 Liter glass flasks

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**   located in a water bath and electronically monitored for
**   oxygen consumption. Test material was tested in triplicate,
**   controls and blanks were tested in duplicate. Test material
**   (hydrotreated heavy paraffinic petroleum distillates, HHP)
**   concentration was approximately  44 mg/l, equivalent to a
**   theoretical oxygen demand (ThOD) of 148 mg/l.  Test material
**   was weighed onto a Gelman type A/E 13 mm glass fiber filter
**   which was then added to each respirometer flask. Sodium
**   benzoate (positive control) concentration was 53.54 mg/l,
**   and was added using an aliquot of a stock solution.
**   Test temperature was 22 ± 1°C. All test vessels were stirred
**   constantly for 28 days using magnetic stir bars and plates.
F008 IUC4
F020 3652
EOR
F002 40
F010 3.5
F004 7
F005 RE
F006 BP International Limited. (1990)
**   Assessment of Ready Biodegradability (Modified Sturm Test).
**   Project No. 301/64; Report No. AT301/064.
F007 BP International Limited. (1990)
**   Assessment of Ready Biodegradability (Modified Sturm Test).
**   Project No. 301/64; Report No. AT301/064.
F008 IUC4
F020 3653
EOR
F002 40
F010 3.5
F004 7
F005 RL
F006 The study was performed following the 1981 guidelines for
**   OECD 301B.
F007 The study was performed following the 1981 guidelines for
**   OECD 301B.
F008 IUC4
F020 3654
EOR
F002 40
F010 3.5
F004 7
F005 RS
F006 By day 28, the 10 and 20 mg C/L test flasks showed
**   biodegradation of 29% and 22%, respectively.
**          % Degradation     % Degradation     % Degradation
**   Day          Reference   10 ppm            20 ppm
**                      Test  Sub.  Test Sub.
**   10           31          0           1
**   21           89          25          12
**   28           89          2
F007 By day 28, the 10 and 20 mg C/L test flasks showed
**   biodegradation of 29% and 22%, respectively.
**          % Degradation     % Degradation     % Degradation
**   Day          Reference   10 ppm            20 ppm
**                      Test  Sub.  Test Sub.
**   10           31          0           1
```

```
**   21           89          25          12
**   28           89          29          22
**
**   The test material was not readily biodegradable.  Within a
**   period of 28 days, 22 and 29% degradation was observed. The
**   pass limit for this test is 60% within 28 days.
**
**   The reference test substance was degraded to 89% by day 28.
**   The pH of the test cultures (10 mg/l and 20 mg/l) and
**   controls (sodium benzoate standard and negative control)
**   measured on Day 27 were 4.8, 4.8, 4.9, and 5.2,
**   respectively.
F008 IUC4
F020 3655
EOR
F002 40
F010 3.5
F004 7
F005 TC
F006 The test material entered the experimental containers
**   through direct dispersion in water.  Activated sludge
**   bacteria from the Severn Trent Plc sewage treatment plant in
**   Belper, Derbyshire was used as the inoculum.  The sample
**   sludge was hom
F007 The test material entered the experimental containers
**   through direct dispersion in water.  Activated sludge
**   bacteria from the Severn Trent Plc sewage treatment plant in
**   Belper, Derbyshire was used as the inoculum.  The sample
**   sludge was homogenized in a mixer for 10 minutes prior to a
**   solid settling phase and a subsequent filtering of the
**   supernatant for use.  The experimental containers had an
**   inoculum concentration of 1%.
**   The exposures lasted for a period of 28 days.  The
**   experimental containers were 5 liter glass culture vessels,
**   containing 3 liters of a mixture of nutrient medium, test
**   material, and inoculum.  Test conditions were run in
**   darkness at a constant temperature of 21°C. Nutrient medium
**   was prepared according to the OECD guideline recipe using
**   tap water purified by ion exchange and reverse osmosis.
**   A series of both two controls and two test material
**   concentrations were run.  The controls consisted of a group
**   with just the culture medium and the inoculum and a group
**   with culture medium, inoculum, and 20 mg/l Sodium benzoate
**   (C6H5 * COONa).  The two test concentrations of test
**   material were 10 and 20 mg/l.
**   All culture vessels were sealed and aerated with CO2 free
**   air at a rate of about 2 bubbles per second.  Additionally,
**   the solution was continuously stirred by magnetic stirrers.
**   Samples were taken from the first CO2 absorber vessel on
**   Days 0, 1, 2, 3, 6, 8, 10, 14, 16, 21, 23, 27, and 28.
**   Samples were taken from the second absorber vessel on Days 0
**   and 28.  The absorbers were made up of 500 ml Dreschel
**   bottles filled with 350 ml of 0.05M NaOH.  The solution was
**   prepared using purified, degassed water.  On day 27, the pH
**   of each vessel was measured and 1 ml of concentrated HCl was
**   added to drive off inorganic carbonate.  CO2 production (as
**   inorganic carbon) was measured by an Ionics 555 TOC Analyzer
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**   in triplicate.
F008 IUC4
F020 3656
EOR
F002 40
F010 3.5
F004 18
F005 RE
F006 BP International Limited. (1991)
**   Mineral Hydrocarbon Oil: Biodegradability by CEC Method
**   L-33-T-82.
**   Report No. BL3975/B, Performing Laboratory Study No. T930/A.
F007 BP International Limited. (1991)
**   Mineral Hydrocarbon Oil: Biodegradability by CEC Method
**   L-33-T-82.
**   Report No. BL3975/B, Performing Laboratory Study No. T930/A.
F008 IUC4
F020 3657
EOR
F002 40
F010 3.5
F004 18
F005 RL
F006 The CEC method is not a test of ready or inherent
**   biodegradability, nor do the test results provide a reliable
**   measure of the extent of ultimate biodegradability, or
**   mineralization.  These test results can only indicate
**   primary biodegradati
F007 The CEC method is not a test of ready or inherent
**   biodegradability, nor do the test results provide a reliable
**   measure of the extent of ultimate biodegradability, or
**   mineralization.  These test results can only indicate
**   primary biodegradation, i.e., some loss of oil based on
**   concentration analysis of the parent base oil over the
**   course of the study.
F008 IUC4
F020 3658
EOR
F002 40
F010 3.5
F004 18
F005 RS
F006 By day 21, biodegradation of the test substance was 63%,
**   65%, and 61% in the individual flasks.  The mean
**   biodegradation was 63%.
**                        % Biodegradation
**    Reference Material             Test Substance
**   Day    Rep1  Rep2  Rep3        R
F007 By day 21, biodegradation of the test substance was 63%,
**   65%, and 61% in the individual flasks.  The mean
**   biodegradation was 63%.
**                        % Biodegradation
**    Reference Material             Test Substance
**   Day    Rep1  Rep2  Rep3        Rep1  Rep2  Rep3 21     27    29    30
      63    65    61
**
**   Mean:        29                    63
```

** Biodegradation of the reference material was 27%, 29%, and
** 30% in the individual flasks, and the mean biodegradation
** was 29%.
** There were no apparent deviations from the given method.
F008 IUC4
F020 3659
EOR
F002 40
F010 3.5
F004 18
F005 TC
F006 Settled activated sludge acquired from Buckland Sewage
** Treatment Works, Milber, Newton Abbot, Devon, was utilized
** as the inoculum. The inoculum was normally between 105 and
** 107 Colony Forming Units (CFU)/ml. Bacteria were enumerated
** by Di
F007 Settled activated sludge acquired from Buckland Sewage
** Treatment Works, Milber, Newton Abbot, Devon, was utilized
** as the inoculum. The inoculum was normally between 105 and
** 107 Colony Forming Units (CFU)/ml. Bacteria were enumerated
** by Dip Slide (Oxoid, TTC Red Spot) and incubated at 25 ±1°C
** until sufficient colonies were visible to enable counting.
** The inoculum was used in the experiment at a rate of 1 ml
** per flask.
** The test medium was prepared following the formula specified
** in ISO Standard 7827. Mother solutions of the test
** substance and reference oil were prepared by adding 150 g of
** test or reference substance to 1 liter of A113
** (1,1,2-trichlorotrifluoroethane). The negative control
** reference substance was white oil, R.L. 110 (Brixham test
** substance #T071). The test design consisted of 5 test flasks
** containing 150 ml of test medium, 1 ml inoculum, and 50 ml
** of test substance mother solution; 5 reference flasks
** containing 150 ml of test medium, 1 ml inoculum, and 50 ml
** of reference substance mother solution; 2 blank flasks
** containing 150 ml of test medium and 1 ml inoculum; and 1
** poisoned flask prepared identical as the test flasks but
** contained 1 ml of HgCl2. Incubation flasks were 500-ml
** conical flasks fitted with foam plugs.
** On day 0 of the test, two blank flasks, two test flasks, and
** two reference flasks were sacrificed for analysis of
** residual oil content by infrared spectrophotometry (see
** analysis procedure below). The remaining flasks were placed
** on an orbital incubator and maintained at 25 ± 1°C for 21
** days. On day 21, the contents of all flasks were analyzed
** for residual oil content.
**
** Analysis Procedure:
** Residual oil content (%) in each flask was analyzed using a
** method suitable for the determination of hydrocarbon
** lubricants in water samples. Lubricants were extracted from
** water using 1,1,2 trichlorotrifluoroethane and were analyzed
** using infrared spectrophotometry. The samples were
** quantified against known standards of the lubricant using
** the maximum absorption of the CH3-CH2 band at 2930 ± 10
** cm-1.
** Percent test substance degraded was calculated as

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**
**   % (ROC) poisoned flask - % ROC test flask  x  100
**                      %ROC poisoned flask
F008 IUC4
F020 3660
EOR
F002 40
F010 3.5
F004 31
F005 RE
F006 BP International Limited. (1990)
**   Assessment of Ready Biodegradability (Modified Sturm Test).
**   Project No. 301/10; Report No. AT301/030.
F007 BP International Limited. (1990)
**   Assessment of Ready Biodegradability (Modified Sturm Test).
**   Project No. 301/10; Report No. AT301/030.
F008 IUC4
F020 3661
EOR
F002 40
F010 3.5
F004 31
F005 RE
F006 BP International Limited. (1990)
**   Assessment of Ready Biodegradability (Modified Sturm Test).
**   Project No. 301/11; Report No. AT301/031.
F007 BP International Limited. (1990)
**   Assessment of Ready Biodegradability (Modified Sturm Test).
**   Project No. 301/11; Report No. AT301/031.
F008 IUC4
F020 3662
EOR
F002 40
F010 3.5
F004 31
F005 RE
F006 BP International Limited. (1990)
**   Assessment of Ready Biodegradability (Modified Sturm Test).
**   Project No. 301/12; Report No. AT301/034.
F007 BP International Limited. (1990)
**   Assessment of Ready Biodegradability (Modified Sturm Test).
**   Project No. 301/12; Report No. AT301/034.
F008 IUC4
F020 3663
EOR
F002 40
F010 3.5
F004 31
F005 RE
F006 BP International Limited. (1990)
**   Assessment of Ready Biodegradability (Modified Sturm Test).
**   Project No. 301/13; Report No. AT301/032.
F007 BP International Limited. (1990)
**   Assessment of Ready Biodegradability (Modified Sturm Test).
**   Project No. 301/13; Report No. AT301/032.
F008 IUC4
F020 3664
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EOR
F002 40
F010 3.5
F004 31
F005 RE
F006 BP International Limited. (1990)
**   Assessment of Ready Biodegradability (Modified Sturm Test).
**   Project No. 301/15; Report No. AT301/035.
F007 BP International Limited. (1990)
**   Assessment of Ready Biodegradability (Modified Sturm Test).
**   Project No. 301/15; Report No. AT301/035.
F008 IUC4
F020 3665
EOR
F002 40
F010 3.5
F004 31
F005 RE
F006 BP International Limited. (1990)
**   Assessment of Ready Biodegradability (Modified Sturm Test).
**   Project No. 301/16; Report No. AT301/036.
F007 BP International Limited. (1990)
**   Assessment of Ready Biodegradability (Modified Sturm Test).
**   Project No. 301/16; Report No. AT301/036.
F008 IUC4
F020 3666
EOR
F002 40
F010 3.5
F004 31
F005 RE
F006 BP International Limited. (1990)
**   Assessment of Ready Biodegradability (Modified Sturm Test).
**   Project No. 301/60; Report No. AT301/038.
F007 BP International Limited. (1990)
**   Assessment of Ready Biodegradability (Modified Sturm Test).
**   Project No. 301/60; Report No. AT301/038.
F008 IUC4
F020 3667
EOR
F002 40
F010 3.5
F004 31
F005 RE
F006 BP International Limited. (1990)
**   Assessment of Ready Biodegradability (Modified Sturm Test).
**   Project No. 301/64; Report No. AT301/064.
F007 BP International Limited. (1990)
**   Assessment of Ready Biodegradability (Modified Sturm Test).
**   Project No. 301/64; Report No. AT301/064.
F008 IUC4
F020 3668
EOR
F002 40
F010 3.5
F004 31
F005 RE

F006 BP International Limited. (1990)
** Assessment of Ready Biodegradability (Modified Sturm Test).
** Project No. 301/9; Report No. AT301/029.
F007 BP International Limited. (1990)
** Assessment of Ready Biodegradability (Modified Sturm Test).
** Project No. 301/9; Report No. AT301/029.
F008 IUC4
F020 3669
EOR
F002 40
F010 3.5
F004 31
F005 RE
F006 BP International Limited. (1990)
** Assessment of Ready Biodegradability (Modified Sturm Test).
** Project No. 301/59; Report No. AT301/037.
F007 BP International Limited. (1990)
** Assessment of Ready Biodegradability (Modified Sturm Test).
** Project No. 301/59; Report No. AT301/037.
F008 IUC4
F020 3670
EOR
F002 40
F010 3.5
F004 31
F005 RE
F006 BP International Limited. (1991)
** Mineral Hydrocarbon Oil: Biodegradability by CEC Method
** L-33-T-82.
** Report No. BL3823/B, Performing Laboratory Study No. T119/A.
F007 BP International Limited. (1991)
** Mineral Hydrocarbon Oil: Biodegradability by CEC Method
** L-33-T-82.
** Report No. BL3823/B, Performing Laboratory Study No. T119/A.
F008 IUC4
F020 3671
EOR
F002 40
F010 3.5
F004 31
F005 RE
F006 BP International Limited. (1991)
** Mineral Hydrocarbon Oil: Biodegradability by CEC Method
** L-33-T-82.
** Report No. BL3820/B, Performing Laboratory Study No. T116/A.
F007 BP International Limited. (1991)
** Mineral Hydrocarbon Oil: Biodegradability by CEC Method
** L-33-T-82.
** Report No. BL3820/B, Performing Laboratory Study No. T116/A.
F008 IUC4
F020 3672
EOR
F002 40
F010 3.5
F004 31
F005 RE
F006 BP International Limited. (1991)

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**   Mineral Hydrocarbon Oil: Biodegradability by CEC Method
**   L-33-T-82.
**   Report No. BL3824/B, Performing Laboratory Study No. T120/A.
F007 BP International Limited. (1991)
**   Mineral Hydrocarbon Oil: Biodegradability by CEC Method
**   L-33-T-82.
**   Report No. BL3824/B, Performing Laboratory Study No. T120/A.
F008 IUC4
F020 3673
EOR
F002 40
F010 3.5
F004 31
F005 RE
F006 BP International Limited. (1991)
**   Mineral Hydrocarbon Oil: Biodegradability by CEC Method
**   L-33-T-82.
**   Report No. BL3825/B, Performing Laboratory Study No. T121/A.
F007 BP International Limited. (1991)
**   Mineral Hydrocarbon Oil: Biodegradability by CEC Method
**   L-33-T-82.
**   Report No. BL3825/B, Performing Laboratory Study No. T121/A.
F008 IUC4
F020 3674
EOR
F002 40
F010 3.5
F004 31
F005 RE
F006 BP International Limited. (1991)
**   Mineral Hydrocarbon Oil: Biodegradability by CEC Method
**   L-33-T-82.
**   Report No. BL3970/B, Performing Laboratory Study No. T651/A.
F007 BP International Limited. (1991)
**   Mineral Hydrocarbon Oil: Biodegradability by CEC Method
**   L-33-T-82.
**   Report No. BL3970/B, Performing Laboratory Study No. T651/A.
F008 IUC4
F020 3675
EOR
F002 40
F010 3.5
F004 31
F005 RE
F006 BP International Limited. (1991)
**   Mineral Hydrocarbon Oil: Biodegradability by CEC Method
**   L-33-T-82.
**   Report No. BL3971/B, Performing Laboratory Study No. T652/A.
F007 BP International Limited. (1991)
**   Mineral Hydrocarbon Oil: Biodegradability by CEC Method
**   L-33-T-82.
**   Report No. BL3971/B, Performing Laboratory Study No. T652/A.
F008 IUC4
F020 3676
EOR
F002 40
F010 3.5
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F004 31
F005 RE
F006 BP International Limited. (1991)
** Mineral Hydrocarbon Oil: Biodegradability by CEC Method
** L-33-T-82.
** Report No. BL3975/B, Performing Laboratory Study No. T930/A.
F007 BP International Limited. (1991)
** Mineral Hydrocarbon Oil: Biodegradability by CEC Method
** L-33-T-82.
** Report No. BL3975/B, Performing Laboratory Study No. T930/A.
F008 IUC4
F020 3677
EOR
F002 40
F010 3.5
F004 31
F005 RE
F006 BP International Limited. (1991)
** Mineral Hydrocarbon Oil: Biodegradability by CEC Method
** L-33-T-82.
** Report No. BL3819/B, Performing Laboratory Study No. T115/A.
F007 BP International Limited. (1991)
** Mineral Hydrocarbon Oil: Biodegradability by CEC Method
** L-33-T-82.
** Report No. BL3819/B, Performing Laboratory Study No. T115/A.
F008 IUC4
F020 3678
EOR
F002 40
F010 3.5
F004 31
F005 RE
F006 BP International Limited. (1991)
** Mineral Hydrocarbon Oil: Biodegradability by CEC Method
** L-33-T-82.
** Report No. BL3821/B, Performing Laboratory Study No. T117/A.
F007 BP International Limited. (1991)
** Mineral Hydrocarbon Oil: Biodegradability by CEC Method
** L-33-T-82.
** Report No. BL3821/B, Performing Laboratory Study No. T117/A.
F008 IUC4
F020 3679
EOR
F002 40
F010 3.5
F004 31
F005 RE
F006 BP International Limited. (1991)
** Mineral Hydrocarbon Oil: Biodegradability by CEC Method
** L-33-T-82.
** Report No. BL3822/B, Performing Laboratory Study No. T118/A.
F007 BP International Limited. (1991)
** Mineral Hydrocarbon Oil: Biodegradability by CEC Method
** L-33-T-82.
** Report No. BL3822/B, Performing Laboratory Study No. T118/A.
F008 IUC4
F020 3680

EOR
F002 40
F010 3.5
F004 31
F005 RE
F006 BP International Limited. (1991)
** Mineral Hydrocarbon Oil: Biodegradability by CEC Method
** L-33-T-82.
** Report No. BL3826/B, Performing Laboratory Study No. T122/A.
F007 BP International Limited. (1991)
** Mineral Hydrocarbon Oil: Biodegradability by CEC Method
** L-33-T-82.
** Report No. BL3826/B, Performing Laboratory Study No. T122/A.
F008 IUC4
F020 3681
EOR
F002 40
F010 3.5
F004 31
F005 RE
F006 Exxon Biomedical Sciences, Inc. (1995)
** Ready Biodegradability, Manometric Respirometry.
** Study #107194A.
F007 Exxon Biomedical Sciences, Inc. (1995)
** Ready Biodegradability, Manometric Respirometry.
** Study #107194A.
F008 IUC4
F020 3682
EOR
F002 40
F010 3.5
F004 31
F005 RE
F006 Exxon Biomedical Sciences, Inc. (1995)
** Ready Biodegradability, Manometric Respirometry.
** Study #123694A.
F007 Exxon Biomedical Sciences, Inc. (1995)
** Ready Biodegradability, Manometric Respirometry.
** Study #123694A.
F008 IUC4
F020 3683
EOR
F002 40
F010 3.5
F004 31
F005 RE
F006 Exxon Biomedical Sciences, Inc. (1995)
** Ready Biodegradability, Manometric Respirometry.
** Study #107094A.
F007 Exxon Biomedical Sciences, Inc. (1995)
** Ready Biodegradability, Manometric Respirometry.
** Study #107094A.
F008 IUC4
F020 3684
EOR
F002 40
F010 3.5

F004 31
F005 RE
F006 Exxon Biomedical Sciences, Inc. (1995)
** Ready Biodegradability, Manometric Respirometry.
** Study #198194A.
F007 Exxon Biomedical Sciences, Inc. (1995)
** Ready Biodegradability, Manometric Respirometry.
** Study #198194A.
F008 IUC4
F020 3685
EOR
F002 40
F010 3.5
F004 31
F005 RE
F006 Shell Research Ltd. (1986)
** Base Oils: An Assessment of Ready Biodegradability. Report
** No. SBGR.86.137.
F007 Shell Research Ltd. (1986)
** Base Oils: An Assessment of Ready Biodegradability. Report
** No. SBGR.86.137.
F008 IUC4
F020 3686
EOR
F002 40
F010 3.5
F004 31
F005 RE
F006 Shell Research Ltd. (1987)
** Base Oil: An Assessment of Ready Biodegradability. Report
** No. SBGR.87.259.
F007 Shell Research Ltd. (1987)
** Base Oil: An Assessment of Ready Biodegradability. Report
** No. SBGR.87.259.
F008 IUC4
F020 3687
EOR
F002 40
F010 3.5
F004 31
F005 RM
F006 28 biodegradability studies have been reported for base
** oils.
** In the preceding paragraphs a full study description is
** given for each of the methods that have been used.
**
** Based on the results of ultimate biodegradability tests
** using modified
F007 28 biodegradability studies have been reported for base
** oils.
** In the preceding paragraphs a full study description is
** given for each of the methods that have been used.
**
** Based on the results of ultimate biodegradability tests
** using modified Sturm and manometric respirometry testing
** these base oils are expected to be, for the most part,
** inherently biodegradable.

** Results of primary biodegradability testing using the CEC
** test method indicate that transformation of parent base oil
** due to biological activity occurs to a varying extent,
** ranging from 13% to 79% loss of original concentrations of
** tested base oils.
**
** Summarized data for all studies (including those described
** in
** the preceding paras) are tabulated below
**

** Method*	(%)	Biodeg. Yes/No	Biodegradable Ref.
**
** Distillates, solvent-refined heavy paraffinic (64741-88-4)			
** OECD 301B**	22, 11	No	30
** OECD 301B	15, 12	No	25
** OECD 301B	8, 8	No	28
** OECD 301B	3, 11	No	29
** OECD 301B	12, 11	No	26
** OECD 301B	9, 8	No	27
** CEC L-33-T-82	72	Yes	57
** CEC L-33-T-82	71	Yes	58
** CEC L-33-T-82	53	Yes	49
** CEC L-33-T-82	79	Yes	50
** CEC L-33-T-82	64	Yes	59
** CEC L-33-T-82	51	Yes	52
**			
** Distillates, solvent-refined light paraffinic (64741-89-5)			
** OECD 301B	29, 22	No	32
** OECD 301B	17, 17	No	33
** CEC L-33-T-82	63	Yes	55
** CEC L-33-T-82	75	Yes	56
**			
** Solvent de-asphalted Bright stock (64741-95-3)			
** OECD 301B	11, 4	No	31
** CEC L-33-T-82	17	No	54
** Distillates, hydrotreated or solvent refined light			
** naphthenic (64741-97-5)			
** 84\449\EEC, C5	1.5	No	103
**			
** Solvent-refined residual oil (64742-01-4)			
** OECD 301B	4, 2	No	No Ref
** OECD 301B	5, 5	No	44
** CEC L-33-T-82	45	Yes	51
** CEC L-33-T-82	13	No	53
**			
** Distillates, hydrotreated or solvent refined light			
** naphthenic (64742-53-6)			
** OECD 301F	42	Yes	80
**			
** Distillates, hydrotreated heavy paraffinic (64742-54-7)			
** OECD 301F	31	Yes	83
**			
** Distillates, solvent dewaxed light paraffinic (64742-56-9)			
** OECD 301F	50	Yes	82
**			
** Distillate, solvent-dewaxed heavy paraffinic (64742-65-0)			

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**    84\449\EEC, C5    23    Yes         102
**    OECD 301F   38    Yes         81
**
**   White oil, (8042-47-5)
**    OECD 301B***      -, 24 Yes         cited in 71
**    CEC L-33-T-82     0     No          cited in 71
**
**   *      Methods used are:
**    OECD 301B   Ready, Sturm test
**    OECD 301F   Ready, Manometric method
**    CEC L-33-T-82     CEC Test
**    84\449\EEC, C5    Ready, Sturm Test
**
**   **     For method OECD 301B the two values given for
**    biodegradation are for test material concentrations   of 10 and 20 ppm.
**
**   ***    Value only available for 20 ppm concentration
F008 IUC4
F020 3688
EOR
F002 40
F010 4.1
F004 1
F005 RE
F006 BP International Limited. (1990)
**   The Acute Toxicity to Rainbow Trout (Salmo gairdneri).
**   Project No. 301/65;
**   Report No. AT301/044.
F007 BP International Limited. (1990)
**   The Acute Toxicity to Rainbow Trout (Salmo gairdneri).
**   Project No. 301/65;
**   Report No. AT301/044.
F008 IUC4
F020 3689
EOR
F002 40
F010 4.1
F004 1
F005 RL
F006 Only one concentration of the test substance was tested.
**   Results of chemical analyses of test substance
**   concentrations were not reported.
F007 Only one concentration of the test substance was tested.
**   Results of chemical analyses of test substance
**   concentrations were not reported.
F008 IUC4
F020 3690
EOR
F002 40
F010 4.1
F004 1
F005 RS
F006 No mortality at 96 hours in the 0 and 1000 mg/l groups.
**
**   96 hrs-LL0 = 1000 mg/l, based on nominal loading rates.
**
**   Only one concentration was tested in the limit test.  The
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**   report states that water samples were taken at 0, 24, and 96
**   hours f
F007 No mortality at 96 hours in the 0 and 1000 mg/l groups.
**
**   96 hrs-LL0 = 1000 mg/l, based on nominal loading rates.
**
**   Only one concentration was tested in the limit test.  The
**   report states that water samples were taken at 0, 24, and 96
**   hours for analytical verification of test concentrations,
**   but results of any analyses were not reported.
F008 IUC4
F020 3691
EOR
F002 40
F010 4.1
F004 1
F005 TC
F006 Daily renewal of the test media ensured that test material
**   levels were maintained at the exposure concentrations.  The
**   test media was introduced into the exposure vessels through
**   direct dispersion in water.  Shielded propeller-stirrers
**   were
F007 Daily renewal of the test media ensured that test material
**   levels were maintained at the exposure concentrations.  The
**   test media was introduced into the exposure vessels through
**   direct dispersion in water.  Shielded propeller-stirrers
**   were utilized to aid in the dispersion of the test material.
**    Observations indicated that the test material was well
**   dispersed throughout the experiment.
**   20 ml water samples were drawn from the exposure vessels via
**   a glass syringe and delivered to a storage vessel.  The
**   syringe was then rinsed with 20 ml of
**   1,1,2-trichlorotrifluoroethane.  Subsequently, the rinse was
**   mixed with the sample prior to storage.  Water samples were
**   collected at 0, 24, and 96 hours into the experiment.
**   Samples were stored at 4°C in glass containers until BP
**   International Limited analyzed them.
**   Exposure vessels were glass aquaria equipped with shielded
**   propeller-stirrers containing 20 liters of test media.  The
**   stirrers rotated at 2000 rpm.  10 fish were housed in each
**   vessel and 20 fish were exposed at the experimental
**   concentration.  The experimental groups included a control
**   and a group exposed to a concentration of 1000 mg/l.  The
**   exposure was conducted under a 16 hour/8 hour, light/dark
**   photoperiod.
**   The rainbow trout were supplied by Trafalgar Nurseries,
**   Downton, Salisbury, U.K.  The mean length and mean weight
**   (sd) of the experimental fish were 4.8 cm (0.4 cm) and 1.33
**   g (0.49 g), respectively.  Fish were fed commercial trout
**   pellets on a daily basis.  Feeding was discontinued 24 hours
**   prior to the initial exposure.  The fish were laboratory
**   acclimated for 4 days prior to a one week test condition
**   acclimation.  Biomass loading in the test chambers was 0.67
**   g/l.
**   Test water was tap water, dechlorinated through the addition
**   of sodium thiosulfate.  Exposures occurred at 14°C, a
**   hardness of 50 mg/l as CaCO3 and the D.O. level never
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**   dropped below 10.0 mgO2/l.  The pH of the control groups
**   ranged from 7.6-7.7.
F008 IUC4
F020 3692
EOR
F002 40
F010 4.1
F004 15
F005 RE
F006 BP International Limited. (1990)
**   The Acute Toxicity of to Rainbow Trout (Salmo gairdneri).
**   Project No. 301/3;
**   Report No. AT301/023.
F007 BP International Limited. (1990)
**   The Acute Toxicity of to Rainbow Trout (Salmo gairdneri).
**   Project No. 301/3;
**   Report No. AT301/023.
F008 IUC4
F020 3693
EOR
F002 40
F010 4.1
F004 15
F005 RE
F006 BP International Limited. (1990)
**   The Acute Toxicity of to Rainbow Trout (Salmo gairdneri).
**   Project No. 301/7;
**   Report No. AT301/027.
F007 BP International Limited. (1990)
**   The Acute Toxicity of to Rainbow Trout (Salmo gairdneri).
**   Project No. 301/7;
**   Report No. AT301/027.
F008 IUC4
F020 3694
EOR
F002 40
F010 4.1
F004 15
F005 RE
F006 BP International Limited. (1990)
**   The Acute Toxicity to Rainbow Trout (Salmo gairdneri).
**   Project No. 301/2;
**   Report No. AT301/022.
F007 BP International Limited. (1990)
**   The Acute Toxicity to Rainbow Trout (Salmo gairdneri).
**   Project No. 301/2;
**   Report No. AT301/022.
F008 IUC4
F020 3695
EOR
F002 40
F010 4.1
F004 15
F005 RE
F006 BP International Limited. (1990)
**   The Acute Toxicity to Rainbow Trout (Salmo gairdneri).
**   Project No. 301/55;
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**   Report No. AT301/042.
F007 BP International Limited. (1990)
**   The Acute Toxicity to Rainbow Trout (Salmo gairdneri).
**   Project No. 301/55;
**   Report No. AT301/042.
F008 IUC4
F020 3696
EOR
F002 40
F010 4.1
F004 15
F005 RE
F006 BP International Limited. (1990)
**   The Acute Toxicity to Rainbow Trout (Salmo gairdneri).
**   Project No. 301/65;
**   Report No. AT301/044.
F007 BP International Limited. (1990)
**   The Acute Toxicity to Rainbow Trout (Salmo gairdneri).
**   Project No. 301/65;
**   Report No. AT301/044.
F008 IUC4
F020 3697
EOR
F002 40
F010 4.1
F004 15
F005 RE
F006 BP International Limited. (1990)
**   The Acute Toxicity to Rainbow Trout (Salmo gairdneri).
**   Project No. 301/6;
**   Report No. AT301/026.
F007 BP International Limited. (1990)
**   The Acute Toxicity to Rainbow Trout (Salmo gairdneri).
**   Project No. 301/6;
**   Report No. AT301/026.
F008 IUC4
F020 3698
EOR
F002 40
F010 4.1
F004 15
F005 RE
F006 BP International Limited. (1990)
**   The Acute Toxicity to Rainbow Trout (Salmo gairdneri).
**   Project No. 301/1;
**   Report No. AT301/021.
F007 BP International Limited. (1990)
**   The Acute Toxicity to Rainbow Trout (Salmo gairdneri).
**   Project No. 301/1;
**   Report No. AT301/021.
F008 IUC4
F020 3699
EOR
F002 40
F010 4.1
F004 15
F005 RE
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F006 BP International Limited. (1990)
**   The Acute Toxicity to Rainbow Trout (Salmo gairdneri).
**   Project No. 301/4;
**   Report No. AT301/024.
F007 BP International Limited. (1990)
**   The Acute Toxicity to Rainbow Trout (Salmo gairdneri).
**   Project No. 301/4;
**   Report No. AT301/024.
F008 IUC4
F020 3700
EOR
F002 40
F010 4.1
F004 15
F005 RE
F006 BP International Limited. (1990)
**   The Acute Toxicity to Rainbow Trout (Salmo gairdneri).
**   Project No. 301/56;
**   Report No. AT301/043R.
F007 BP International Limited. (1990)
**   The Acute Toxicity to Rainbow Trout (Salmo gairdneri).
**   Project No. 301/56;
**   Report No. AT301/043R.
F008 IUC4
F020 3701
EOR
F002 40
F010 4.1
F004 15
F005 RE
F006 BP International Limited. (1990)
**   The Acute Toxicity to Rainbow Trout (Salmo gairdneri).
**   Project No. 301/8;
**   Report No. AT301/028.
F007 BP International Limited. (1990)
**   The Acute Toxicity to Rainbow Trout (Salmo gairdneri).
**   Project No. 301/8;
**   Report No. AT301/028.
F008 IUC4
F020 3702
EOR
F002 40
F010 4.1
F004 15
F005 RE
F006 BP International Limited. 1990
**   The Acute Toxicity to Rainbow Trout (Salmo gairdneri).
**   Project No. 301/5;
**   Report No. AT301/025.
F007 BP International Limited. 1990
**   The Acute Toxicity to Rainbow Trout (Salmo gairdneri).
**   Project No. 301/5;
**   Report No. AT301/025.
F008 IUC4
F020 3703
EOR
F002 40
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F010 4.1
F004 15
F005 RE
F006 Exxon Biomedical Sciences, Inc. (1995)
**   Fathead Minnow Acute Fish Toxicity Test.
**   Study #101740.
F007 Exxon Biomedical Sciences, Inc. (1995)
**   Fathead Minnow Acute Fish Toxicity Test.
**   Study #101740.
F008 IUC4
F020 3704
EOR
F002 40
F010 4.1
F004 15
F005 RE
F006 Exxon Biomedical Sciences, Inc. (1995)
**   Fathead Minnow Acute Fish Toxicity Test.
**   Study #198140.
F007 Exxon Biomedical Sciences, Inc. (1995)
**   Fathead Minnow Acute Fish Toxicity Test.
**   Study #198140.
F008 IUC4
F020 3705
EOR
F002 40
F010 4.1
F004 15
F005 RE
F006 Exxon Biomedical Sciences, Inc. (1995)
**   Fathead Minnow Acute Fish Toxicity Test.
**   Study #198240.
F007 Exxon Biomedical Sciences, Inc. (1995)
**   Fathead Minnow Acute Fish Toxicity Test.
**   Study #198240.
F008 IUC4
F020 3706
EOR
F002 40
F010 4.1
F004 15
F005 RM
F006 Acute fish toxicity studies have been reported for 14 base
**   oil samples (including the study summarized in full above).
**   The results for all 14 samples are summarized in the table
**   below.
**
**   Result                   Reference
**
**   Salmo gairdneri - semistatic test
F007 Acute fish toxicity studies have been reported for 14 base
**   oil samples (including the study summarized in full above).
**   The results for all 14 samples are summarized in the table
**   below.
**
**   Result                   Reference
**
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```
**   Salmo gairdneri - semistatic test
**   Distillates, solvent-refined heavy paraffinic (64741-88-4)
**
**   7-d LL0=1000 ppm dispersion    48
**   7-d LL0=1000 ppm dispersion    40
**   7-d LL0=1000 ppm dispersion    38
**   7-d LL0=1000 ppm dispersion    39
**   7-d LL0=1000 ppm dispersion    46
**   7-d LL0=1000 ppm dispersion    60
**
**   Distillates, solvent refined light paraffinic (64741-89-5)
**   96-h LL0=1000 ppm dispersion   42
**   7-d LL0=1000 ppm dispersion    45
**
**   Solvent deasphalted bright stock (64741-95-3)
**   96-h LL0=1000 ppm dispersion   47
**
**   Solvent refined residual oil (64742-01-4)
**   7-d LL0=1000 ppm dispersion    43
**   96-h LL0=1000 ppm dispersion   41
**
**   Pimephales promelas - static test
**   Distillates hydrotreated heavy paraffinic (64742-54-7)
**   96-h LL0=100 ppm WAF           78
**
**   Solvent dewaxed residual oil (64742-62-7)
**   96-h LL0=100 ppm WAF           79
**
**   Distillates solvent dewaxed heavy paraffinic (64742-65-0)
**   96-h LL0=100 ppm WAF           77
F008 IUC4
F020 3707
EOR
F002 40
F010 4.2
F004 1
F005 RE
F006 Shell Research Ltd. (1988)
**   Oils: Acute toxicity of four oils to Daphnia magna and
**   Gammarus pulex.
**   Report SBGR.88.075.
F007 Shell Research Ltd. (1988)
**   Oils: Acute toxicity of four oils to Daphnia magna and
**   Gammarus pulex.
**   Report SBGR.88.075.
F008 IUC4
F020 3708
EOR
F002 40
F010 4.2
F004 1
F005 RL
F006 Although test guidelines were not specified and the study
**   was not conducted under GLPs, it was a well-documented
**   study. Analytical monitoring of the oil concentration in the
**   WAFs was not performed. An oily film was visible on the
**   surface of
```

F007 Although test guidelines were not specified and the study
**   was not conducted under GLPs, it was a well-documented
**   study. Analytical monitoring of the oil concentration in the
**   WAFs was not performed. An oily film was visible on the
**   surface of some test solutions apparently as a carryover
**   from the WAF preparations.
F008 IUC4
F020 3709
EOR
F002 40
F010 4.2
F004 1
F005 RS
F006 After 48 hrs no daphnid immobilization was found in any of
**   the concentrations tested.
**
**   The 48 hr EL0 was 10 g/l.
**
**   Control survival was 100% after 48 hrs.
F007 After 48 hrs no daphnid immobilization was found in any of
**   the concentrations tested.
**
**   The 48 hr EL0 was 10 g/l.
**
**   Control survival was 100% after 48 hrs.
F008 IUC4
F020 3710
EOR
F002 40
F010 4.2
F004 1
F005 TC
F006 Individual treatment concentrations were prepared as water
**   accommodated fractions (WAF). Nominal loading rates in the
**   definitive test were 0, 0.01, 0.1, 1, and 10 g/l. Control
**   and dilution water was reconstituted hard water prepared by
**   addi
F007 Individual treatment concentrations were prepared as water
**   accommodated fractions (WAF). Nominal loading rates in the
**   definitive test were 0, 0.01, 0.1, 1, and 10 g/l. Control
**   and dilution water was reconstituted hard water prepared by
**   adding salts to glass-distilled deionized water following
**   EPA guidelines (hardness 174 mg/ml as CaCO3). Test substance
**   was mixed in dilution water for 23 hrs. The mixtures were
**   allowed to stand for 1 hr prior to siphoning off the aqueous
**   phase for testing. Glass flasks (140 ml) were filled with
**   each of the WAFs with 10 daphnids per vessel. The flasks
**   were sealed with glass cover slip to minimize the loss of
**   volatile components of the oil. Test daphnids were <24 hrs
**   old and collected from cultures supplied by the testing
**   laboratory that have been aged between 15 and 35 days. Two
**   replicates per treatment and control were used. Black caps
**   were placed over those flasks in which an oily film was
**   visible on the surface of the test solution so the organisms
**   would avoid the darkened zone and not be trapped in the
**   film. Test temperature was 18 - 22 °C. Dissolved oxygen in
**   the control and highest concentration was 8.8 to 9.1 mg/ml.

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**   pH in the control and highest concentration was 7.7 - 8.0.
F008 IUC4
F020 3711
EOR
F002 40
F010 4.2
F004 2
F005 RE
F006 Shell Research Ltd. (1988)
**   Oils: Acute toxicity of four oils to Daphnia magna and
**   Gammarus pulex.
**   Report SBGR.88.075.
F007 Shell Research Ltd. (1988)
**   Oils: Acute toxicity of four oils to Daphnia magna and
**   Gammarus pulex.
**   Report SBGR.88.075.
F008 IUC4
F020 3712
EOR
F002 40
F010 4.2
F004 2
F005 RL
F006 Although test guidelines were not specified and the study
**   was not conducted under GLPs, it was a well-documented
**   study. Analytical monitoring of the oil concentration in the
**   WAFs was not performed.
F007 Although test guidelines were not specified and the study
**   was not conducted under GLPs, it was a well-documented
**   study. Analytical monitoring of the oil concentration in the
**   WAFs was not performed.
F008 IUC4
F020 3713
EOR
F002 40
F010 4.2
F004 2
F005 RS
F006 No dead organisms were found in any of the test vessels
**   after 96 hours. However, some organisms disappeared from all
**   treatments and control throughout the test. It was assumed
**   that these organisms were eaten by the remaining organisms.
**   The
F007 No dead organisms were found in any of the test vessels
**   after 96 hours. However, some organisms disappeared from all
**   treatments and control throughout the test. It was assumed
**   that these organisms were eaten by the remaining organisms.
**   The numbers of missing animals after 96 hours were 2, 1, 4,
**   5, and 2 in the control, 0.01, 0.1, 1, and 10 g/l WAFs.
**   Since <50% of the organisms were missing in any
**   concentration, and even if these lost animals died as a
**   result of treatment, the 96-hr LL0 was 10 g/l.
F008 IUC4
F020 3714
EOR
F002 40
F010 4.2
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```
F004 2
F005 TC
F006 Individual treatment concentrations were prepared as water
**   accommodated fractions (WAF). Nominal loading rates in the
**   definitive test were 0, 0.01, 0.1, 1, and 10 g/l. Control
**   and dilution water was laboratory mains tap water obtained
**   from
F007 Individual treatment concentrations were prepared as water
**   accommodated fractions (WAF). Nominal loading rates in the
**   definitive test were 0, 0.01, 0.1, 1, and 10 g/l. Control
**   and dilution water was laboratory mains tap water obtained
**   from bore holes, and passed through particle and activated
**   carbon filters (alkalinity 247 mg/ml as CaCO3, hardness 274
**   mg/ml as CaCO3, conductivity 492 mS/cm, pH 7.3). Test
**   substance was mixed in dilution water for 23 hrs. The
**   mixtures were allowed to stand for 1 hr prior to siphoning
**   off the aqueous phase for testing. Fresh WAFs were prepared
**   for each 24-hr renewal. Glass crystallizing dishes (350 ml)
**   were filled with 300 ml of each of the WAFs with 10
**   organisms per dish. Three replicates per treatment and
**   control were used. Test organisms were between 1 and 2 mm in
**   size and collected from a tributary of the River Len at
**   Hollingbourne, Kent, UK. Test temperature was 14 - 18.2 °C.
**   Dissolved oxygen in the control and highest concentration
**   was 7.8 to 9.9 mg/ml. pH in the control and highest
**   concentration was 6.8 - 8.5.
F008 IUC4
F020 3715
EOR
F002 40
F010 4.3
F004 1
F005 RE
F006 BP International Limited. (1990)
**   Assessment of the Algistatic Effect of *****  to Scenedesmus
**   subspicatus. Project No. 301/74.
F007 BP International Limited. (1990)
**   Assessment of the Algistatic Effect of *****  to Scenedesmus
**   subspicatus. Project No. 301/74.
F008 IUC4
F020 3716
EOR
F002 40
F010 4.3
F004 1
F005 RE
F006 BP International Limited. (1990)
**   Assessment of the Algistatic Effect of ***** to Scenedesmus
**   subspicatus. Project No. 301/70.
F007 BP International Limited. (1990)
**   Assessment of the Algistatic Effect of ***** to Scenedesmus
**   subspicatus. Project No. 301/70.
F008 IUC4
F020 3717
EOR
F002 40
F010 4.3
```

```
F004 1
F005 RE
F006 BP International Limited. (1990)
**   Assessment of the Algistatic Effect of ***** to Scenedesmus
**   subspicatus. Project No. 301/72.
F007 BP International Limited. (1990)
**   Assessment of the Algistatic Effect of ***** to Scenedesmus
**   subspicatus. Project No. 301/72.
F008 IUC4
F020 3718
EOR
F002 40
F010 4.3
F004 1
F005 RE
F006 BP International Limited. (1990)
**   Assessment of the Algistatic Effect of ***** to Scenedesmus
**   subspicatus. Project No. 301/76.
F007 BP International Limited. (1990)
**   Assessment of the Algistatic Effect of ***** to Scenedesmus
**   subspicatus. Project No. 301/76.
F008 IUC4
F020 3719
EOR
F002 40
F010 4.3
F004 1
F005 RL
F006 Only one concentration of the test substance was tested.
**   Results of chemical analyses of test substance
**   concentrations were not reported.
F007 Only one concentration of the test substance was tested.
**   Results of chemical analyses of test substance
**   concentrations were not reported.
F008 IUC4
F020 3720
EOR
F002 40
F010 4.3
F004 1
F005 RM
F006 Three other base oil samples have been tested for algal
**   toxicity.
**   The results for all three samples were similar to that
**   described above.
**   Samples tested at one concentration only were as follows:
**
**    CAS No.           Result                  Ref.
**          64741-88-4  96-h
F007 Three other base oil samples have been tested for algal
**   toxicity.
**   The results for all three samples were similar to that
**   described above.
**   Samples tested at one concentration only were as follows:
**
**    CAS No.           Result                  Ref.
**          64741-88-4  96-h LL0 = 50% WAF      34
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**          64741-89-5  96-h LL0 = 50% WAF      35
**    64742-01-4  96-h LL0 = 50% WAF      37
F008 IUC4
F020 3721
EOR
F002 40
F010 4.3
F004 1
F005 RS
F006 No inhibition of growth or growth rate were measured at the
**   single test concentration of 50% WAF.
**   Since there were no observed effects during the study, the
**   96-hour "No Observed Effect Concentration" (NOEC) was 50%
**   WAF.
**   The OECD guideline
F007 No inhibition of growth or growth rate were measured at the
**   single test concentration of 50% WAF.
**   Since there were no observed effects during the study, the
**   96-hour "No Observed Effect Concentration" (NOEC) was 50%
**   WAF.
**   The OECD guideline criterion for cell growth in the control
**   group was met in this experiment.
F008 IUC4
F020 3722
EOR
F002 40
F010 4.3
F004 1
F005 TC
F006 Preparation of the Water Accommodated Fraction (WAF):2.0
**   grams of test material were placed on 2 Liters of culture
**   medium and stirred via magnetic stirrer for a period of 24
**   hours prior to the test.  Culture medium was prepared
**   according to
F007 Preparation of the Water Accommodated Fraction (WAF):2.0
**   grams of test material were placed on 2 Liters of culture
**   medium and stirred via magnetic stirrer for a period of 24
**   hours prior to the test.  Culture medium was prepared
**   according to the guideline formula. After the 24 hour
**   period, stirring was ceased for one hour prior to removing
**   the aqueous phase.  The aqueous phase, representing 100%
**   WAF, was then combined with an equal volume of algal
**   suspension. The algal suspension consisted of Scenedesmus
**   cells taken from a culture in logarithmic growth phase and
**   diluted with growth medium to a cell density of 3.70 x 104
**   cells/ml. The algal species Scenedesmus subspicatus utilized
**   in this study was supplied by the Culture Centre of Algae
**   and Protozoa (CCAP) c/o Institute of Freshwater Ecology,
**   Cumbria, U.K.  Sterile culture medium was inoculated with
**   Scenedesmus and incubated under continuous illumination and
**   aeration at 21°C.
**   10 ml samples of the 50% WAF were taken at times 0 and 96
**   hours.  After adding 10 ml of
**   1,1,2-trichlorotrifluoroethane, the samples were stored at
**   4°C until analyzed. Analytical results were not reported.
**   500 ml of the algal suspension were added to 500 ml of 100%
**   WAF to make the test solution.  100 ml of the test solution
```

** was contained in a loosely stoppered 250 ml conical flask.
** All flasks were incubated and shaken at approximately 100
** rpm in an orbital shaker. 6 replicates of a single test
** concentration and 3 replicates of a control were examined in
** this study. The flasks were housed under a 24 hour light
** photoperiod at an intensity of approximately 7,000 lux and a
** constant temperature of 24°C. No aeration was supplied
** during the study, however, gas exchange and algal cell
** suspension was maintained by the orbital shaker. Samples
** were taken for the determination of algal growth every 24
** hours beginning at hour 0 and ending at hour 96.
** Absorbances were measured at 665 nm with a Jenway 610
** Spectrophotometer. At the initiation and completion of the
** experiment, the cell densities of the control cultures were
** determined through direct counting aided by a
** hemacytometer. The pH of all control and test flasks was
** taken at 0 and 96 hours. The pH at the beginning and end of
** the experiment in all groups ranged from 8.3 to 8.5 and 9.4
** to 9.9, respectively. The area under the curve and growth
** rate were taken as indices of algal growth and were
** calculated using the absorbance readings. Percent
** inhibition values were calculated for area under the curve
** and growth rate.
F008 IUC4
F020 3723
EOR
F002 40
F010 4.5.2
F004 1
F005 RE
F006 BP Oil Europe. (1995)
** Daphnia magna Reproduction Test. SPL Project No. 692/038.
F007 BP Oil Europe. (1995)
** Daphnia magna Reproduction Test. SPL Project No. 692/038.
F008 IUC4
F020 3724
EOR
F002 40
F010 4.5.2
F004 1
F005 RL
F006 The analytical results provided no definitive evidence of
** stability of the test preparations. Only two test
** concentrations were run.
F007 The analytical results provided no definitive evidence of
** stability of the test preparations. Only two test
** concentrations were run.
F008 IUC4
F020 3725
EOR
F002 40
F010 4.5.2
F004 1
F005 RS
F006 After 14 and 21 days of exposure, there were no
** statistically significant differences between the control
** group and the 10 and 1000 mg/ml WAF test groups in terms of

```
**   survival or reproduction (young produced per adult).  In
**   addition, there w
F007 After 14 and 21 days of exposure, there were no
**   statistically significant differences between the control
**   group and the 10 and 1000 mg/ml WAF test groups in terms of
**   survival or reproduction (young produced per adult).  In
**   addition, there were no apparent effects on the F1
**   generation produced during the test.  The numbers of
**   unhatched eggs and dead young were low in all treatment
**   groups.
**
**   The NOEC for survival and reproduction was the maximum test
**   concentration, 1000 mg/ml WAF.
**
**   The test met the validation criteria for 1) dissolved oxygen
**    at least 60%, 2) pH deviation not greater than 0.3, 3)
**   control mortality not greater than 20%, 4) first young
**   (control group) within 9 days, 5) cumulative young per
**   female (control group) at least 20 after 14 days and at
**   least 40 after 21 days, and 6) number of broods per control
**   group at least 3.
F008 IUC4
F020 3726
EOR
F002 40
F010 4.5.2
F004 1
F005 TC
F006 Preparation of the WAF:
**   20 and 2000 mg of test material were each separately placed
**   in 2 liters of reconstituted water (water hardness
**   approximately 270 mg/ml as CaCO2) and stirred via magnetic
**   stirrer for a period of 24 hours prior to the
F007 Preparation of the WAF:
**   20 and 2000 mg of test material were each separately placed
**   in 2 liters of reconstituted water (water hardness
**   approximately 270 mg/ml as CaCO2) and stirred via magnetic
**   stirrer for a period of 24 hours prior to the test.  After
**   the 24-hour period, stirring was ceased for one hour prior
**   to removing the aqueous phase.
**
**   Test Organism Culture:
**   Adult Daphnia magna were maintained in polypropylene vessels
**   containing approximately 2 liters of reconstituted water at
**   a
**   temperature of 21°C.  The organisms were supplied by the
**   Institut National de Recherche Appliquée (IRCHA) France.
**   The lighting was held at 16:8 hour light:dark
**   photoperiod.  Gravid adults were isolated 24 hours prior to
**   the initiation of the test, the young daphnids produced
**   overnight were removed and utilized for testing.
**
**   Test Procedure:
**   The aqueous phase of each WAF was removed and 400-ml
**   aliquots were apportioned to five, 500-ml glass flasks.  A
**   similar number of control flasks containing reconstituted
**   water also were prepared.  The fifth flask from each group
```

** was taken for Total Organic Carbon analysis of the exposure
** media. At the start of the test, 10 daphnids were placed
** within each test flask, and all flasks were covered to
** reduce evaporation. Each vessel received approximately 3.75
** x 109 cells/ml of a mixed unicellular algae culture as a
** daily feeding. Fresh WAFs were prepared on days 0, 2, 4, 7,
** 9, 11, 14, 16, and 18, and the adult daphnids were
** transferred from the old to the fresh solutions. The numbers
** of live and dead Daphnia of the parental generation were
** counted daily. At each test media renewal, Daphnia with
** eggs or young in the brood pouch, discarded unhatched eggs,
** and the number of live and dead filial Daphnia were counted.
**
**
** Temperature was recorded daily for the duration of the
** experiment, while dissolved oxygen and pH were recorded
** prior to and after each media renewal. Measurements of TOC
** were made in the fresh and old test solutions 3 times a week
** over 21 days. Dissolved oxygen in the control, 10, and 1000
** mg/ml WAF groups ranged from 7.9 to 8.3, from 7.9 to 8.3,
** and from 7.8 to 8.3, respectively. Water pH in the control,
** 10, and 1000 mg/ml WAF groups ranged from 7.7 to 7.8, from
** 7.7 to 7.8, and from 7.7 to 7.8, respectively. The
** temperature within all test groups remained constant at 21.0
** °C. The results of the TOC analysis did not demonstrate a
** direct relationship with WAF concentration, and in many
** cases the TOC of the control water was higher than that of
** the test groups. The TOC in the old media tended to be
** higher than fresh solutions.
F008 IUC4
F020 3727
EOR
F002 40
F010 4.5.2
F004 12
F005 RE
F006 BP Oil Europe. (1995)
** Daphnia magna Reproduction Test. SPL Project No. 692/037.
F007 BP Oil Europe. (1995)
** Daphnia magna Reproduction Test. SPL Project No. 692/037.
F008 IUC4
F020 3728
EOR
F002 40
F010 4.5.2
F004 12
F005 RE
F006 BP Oil Europe. (1995)
** Daphnia magna Reproduction Test. SPL Project No. 692/039.
F007 BP Oil Europe. (1995)
** Daphnia magna Reproduction Test. SPL Project No. 692/039.
F008 IUC4
F020 3729
EOR
F002 40
F010 4.5.2
F004 12

F005 RE
F006 BP Oil Europe. (1995)
** Daphnia magna Reproduction Test. SPL Project No. 692/040.
F007 BP Oil Europe. (1995)
** Daphnia magna Reproduction Test. SPL Project No. 692/040.
F008 IUC4
F020 3730
EOR
F002 40
F010 4.5.2
F004 12
F005 RE
F006 BP Oil Europe. (1995)
** Daphnia magna Reproduction Test. SPL Project No. 692/041.
F007 BP Oil Europe. (1995)
** Daphnia magna Reproduction Test. SPL Project No. 692/041.
F008 IUC4
F020 3731
EOR
F002 40
F010 4.5.2
F004 12
F005 RE
F006 BP Oil Europe. (1995)
** Daphnia magna Reproduction Test. SPL Project No. 692/042.
F007 BP Oil Europe. (1995)
** Daphnia magna Reproduction Test. SPL Project No. 692/042.
F008 IUC4
F020 3732
EOR
F002 40
F010 4.5.2
F004 12
F005 RE
F006 BP Oil Europe. (1995)
** Daphnia magna Reproduction Test. SPL Project No. 692/036.
F007 BP Oil Europe. (1995)
** Daphnia magna Reproduction Test. SPL Project No. 692/036.
F008 IUC4
F020 3733
EOR
F002 40
F010 4.5.2
F004 12
F005 RE
F006 Shell Research Limited. (1994)
** Chronic toxicity of water-accommodated fractions to Daphnia
** magna. Experiment #5922.
F007 Shell Research Limited. (1994)
** Chronic toxicity of water-accommodated fractions to Daphnia
** magna. Experiment #5922.
F008 IUC4
F020 3734
EOR
F002 40
F010 4.5.2
F004 12

F005 RE
F006 Shell Research Limited. (1995)
** Chronic toxicity of water accommodated fractions to Daphnia
** magna. Experiment #6215.
F007 Shell Research Limited. (1995)
** Chronic toxicity of water accommodated fractions to Daphnia
** magna. Experiment #6215.
F008 IUC4
F020 3735
EOR
F002 40
F010 4.5.2
F004 12
F005 RM
F006 In addition to the study described above studies have been
** reported for ten further base oil samples in 21 day studies
** with D. magna. In each case OECD guideline 202 part 2 was
** used as the method.
** The results are summarized below:
**
** CAS No.
F007 In addition to the study described above studies have been
** reported for ten further base oil samples in 21 day studies
** with D. magna. In each case OECD guideline 202 part 2 was
** used as the method.
** The results are summarized below:
**

** CAS No.	Result	Reference
** 64741-88-4	21-d LL0 = 1000 mg/l WAF	63
** 64741-88-4	21-d LL0 = 1000 mg/l WAF	64
** 64741-88-4	21-d LL0 = 1000 mg/l WAF	100
** 64741-89-5	21-d LL0 = 1000 mg/l WAF	67
** 64741-89-5	21-d LL0 = 1000 mg/l WAF	61
** 64741-95-3	21-d LL0 = 1000 mg/l WAF	66
** 64742-01-4	21-d LL0 = 1000 mg/l WAF	65
** 64742-53-6	21-d LL0 = 10 mg/l WAF	101
** 64742-55-8	21-d LL0 = 1000 mg/l WAF	100
** 64742-65-0	21-d LL0 = 1000 mg/l WAF	100

**
** Of the reported chronic toxicity studies, no chronic effects
** were observed below 1 mg/l. For all but two studies, no
** chronic toxicity was seen at the highest addition of the
** various base oils tested, which ranged from 1000 to 5000
** mg/l.
F008 IUC4
F020 3736
EOR
F002 40
F010 5.1.1
F004 1
F005 ME
F006 A single dose of undiluted test material (5g/kg) was
** administered orally to 5 male and 5 female fasted rats.
** Food and water was made available ad-lib immediately after
** dosing.
** The animals were observed for clinical signs and mortality
** at h

F007 A single dose of undiluted test material (5g/kg) was
**   administered orally to 5 male and 5 female fasted rats.
**   Food and water was made available ad-lib immediately after
**   dosing.
**   The animals were observed for clinical signs and mortality
**   at hourly intervals for the first 6 hours post dosing and
**   twice daily thereafter. Body weights were recorded prior to
**   fasting, prior to dosing and at 7 and 14 days post dosing.
**   At 14 days, all surviving animals were killed and subjected
**   to a gross necropsy examination.
F008 IUC4
F020 3737
EOR
F002 40
F010 5.1.1
F004 1
F005 RE
F006 American Petroleum Institute (1986)
**   Acute oral toxicity study in rats
**   Acute dermal toxicity study in rabbits
**   Primary dermal irritation study in rabbits
**   Primary eye irritation study in rabbits
**   Dermal sensitization study in Guinea pigs
**   API 84
F007 American Petroleum Institute (1986)
**   Acute oral toxicity study in rats
**   Acute dermal toxicity study in rabbits
**   Primary dermal irritation study in rabbits
**   Primary eye irritation study in rabbits
**   Dermal sensitization study in Guinea pigs
**   API 84-01 Light paraffinic distillate CAS 64741-50-0
**   API Med. Res. Publ.: 33-30595
F008 IUC4
F009 11-09-2010
F020 3738
EOR
F002 40
F010 5.1.1
F004 1
F005 RS
F006 There were no deaths during the study and growth rates were
**   unaffected by dosing. Clinical signs that occurred during
**   the first 3 days included: hypoactivity, diarrhea and a
**   yellow-stained anal area. All animals returned to normal by
**   day
F007 There were no deaths during the study and growth rates were
**   unaffected by dosing. Clinical signs that occurred during
**   the first 3 days included: hypoactivity, diarrhea and a
**   yellow-stained anal area. All animals returned to normal by
**   day 14. At gross necropsy, there were no visible lesions.
F008 IUC31
F020 3739
EOR
F002 40
F010 5.1.1
F004 2
F005 ME

F006 A single dose of undiluted test material (5g/kg) was
** administered orally to 5 male and 5 female fasted rats.
** Food and water was made available ad-lib immediately after
** dosing.
** The animals were observed for clinical signs and mortality
** at h
F007 A single dose of undiluted test material (5g/kg) was
** administered orally to 5 male and 5 female fasted rats.
** Food and water was made available ad-lib immediately after
** dosing.
** The animals were observed for clinical signs and mortality
** at hourly intervals for the first 6 hours post dosing and
** twice daily thereafter. Body weights were recorded prior to
** fasting, prior to dosing and at 7 and 14 days post dosing.
** At 14 days, all surviving animals were killed and subjected
** to a gross necropsy examination.
F008 IUC31
F020 3740
EOR
F002 40
F010 5.1.1
F004 2
F005 RE
F006 American Petroleum Institute (1986)
** Acute oral toxicity study in rats
** Acute dermal toxicity study in rabbits
** Primary dermal irritation study in rabbits
** Primary eye irritation study in rabbits
** Dermal sensitization study in Guinea pigs
** API 83
F007 American Petroleum Institute (1986)
** Acute oral toxicity study in rats
** Acute dermal toxicity study in rabbits
** Primary dermal irritation study in rabbits
** Primary eye irritation study in rabbits
** Dermal sensitization study in Guinea pigs
** API 83-12 Hydrotreated light naphthenic distillate CAS
** 64742-53-6
** API Med. Res. Publ.: 33-30592
F008 IUC4
F009 11-09-2010
F020 3741
EOR
F002 40
F010 5.1.1
F004 2
F005 RS
F006 There were no deaths during the study.
** Clinical signs observed included: hypoactivity,
** yellow-stained anal area, hair loss in the urogenital region
** and swollen hind paws.
** All animals returned to normal by day 3 and had gained
** weight by day
F007 There were no deaths during the study.
** Clinical signs observed included: hypoactivity,
** yellow-stained anal area, hair loss in the urogenital region
** and swollen hind paws.

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**   All animals returned to normal by day 3 and had gained
**   weight by day 7.
**   At necropsy, there were no visible lesions except in one
**   female in which the spleen was cystic, mottled red and tan
**   and had a rough surface. In this animal the pancreas adhered
**   to the entire surface of the spleen.
F008 IUC31
F020 3742
EOR
F002 40
F010 5.1.1
F004 3
F005 RE
F006 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 78-10 paraffinic oil (150
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33105
F007 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 78-10 paraffinic oil (150
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33105
F008 IUC31
F020 3743
EOR
F002 40
F010 5.1.1
F004 3
F005 RE
F006 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 78-5 naphthenic oil (150
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33106
F007 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 78-5 naphthenic oil (150
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33106
F008 IUC31
F020 3744
EOR
F002 40
F010 5.1.1
F004 3
F005 RE
F006 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 78-9 paraffinic oil (70
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33104
F007 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 78-9 paraffinic oil (70
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33104
F008 IUC31
F020 3745
EOR
F002 40
F010 5.1.1
F004 3
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F005 RE
F006 American Petroleum Institute (1982)
** Acute toxicity tests of API sample 79-1 naphthenic oil (90
** SUS/210 °F)
** API Med. Res. Publ. 29-33065
F007 American Petroleum Institute (1982)
** Acute toxicity tests of API sample 79-1 naphthenic oil (90
** SUS/210 °F)
** API Med. Res. Publ. 29-33065
F008 IUC31
F020 3746
EOR
F002 40
F010 5.1.1
F004 3
F005 RE
F006 American Petroleum Institute (1982)
** Acute toxicity tests of API sample 79-3 paraffinic oil (350
** SUS/100 °F)
** API Med. Res. Publ. 29-33067
F007 American Petroleum Institute (1982)
** Acute toxicity tests of API sample 79-3 paraffinic oil (350
** SUS/100 °F)
** API Med. Res. Publ. 29-33067
F008 IUC31
F020 3747
EOR
F002 40
F010 5.1.1
F004 3
F005 RE
F006 American Petroleum Institute (1982)
** Acute toxicity tests of API sample 79-4 paraffinic oil (550
** SUS/100 °F)
** API Med. Res. Publ. 29-33066
F007 American Petroleum Institute (1982)
** Acute toxicity tests of API sample 79-4 paraffinic oil (550
** SUS/100 °F)
** API Med. Res. Publ. 29-33066
F008 IUC31
F020 3748
EOR
F002 40
F010 5.1.1
F004 3
F005 RE
F006 American Petroleum Institute (1982)
** Acute toxicity tests of API sample 79-5 paraffinic oil (800
** SUS/100 °F)
** API Med. Res. Publ. 29-33068
F007 American Petroleum Institute (1982)
** Acute toxicity tests of API sample 79-5 paraffinic oil (800
** SUS/100 °F)
** API Med. Res. Publ. 29-33068
F008 IUC31
F020 3749
EOR

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F002 40
F010 5.1.1
F004 3
F005 RE
F006 American Petroleum Institute (1986)
**   Acute oral toxicity study in rats
**   Acute dermal toxicity study in rabbits
**   Primary dermal irritation study in rabbits
**   Primary eye irritation study in rabbits
**   Dermal sensitization study in guinea pigs
**   API sa
F007 American Petroleum Institute (1986)
**   Acute oral toxicity study in rats
**   Acute dermal toxicity study in rabbits
**   Primary dermal irritation study in rabbits
**   Primary eye irritation study in rabbits
**   Dermal sensitization study in guinea pigs
**   API sample 83-15 hydrotreated heavy naphthenic distillate
**   (CAS 64742-52-5)
**   API Health Environ. Sci. Dep. Rep. 33-32639
F008 IUC31
F020 3750
EOR
F002 40
F010 5.1.1
F004 3
F005 RE
F006 CONCAWE (1997)
**   Lubricating oil basestocks
**   Product dossier No. 97/108
**   CONCAWE, Brussels
F007 CONCAWE (1997)
**   Lubricating oil basestocks
**   Product dossier No. 97/108
**   CONCAWE, Brussels
F008 IUC31
F020 3751
EOR
F002 40
F010 5.1.1
F004 3
F005 RM
F006 CONCAWE summarized the data available on the acute oral
**   toxicity of lubricating oil base stocks.  The data are shown
**   in the following table.
**
**   Paraffinic distillates   CAS No.           Oral LD50    API
**                            (g/kg)         Report No.
**   Solvent dewaxed, light
F007 CONCAWE summarized the data available on the acute oral
**   toxicity of lubricating oil base stocks.  The data are shown
**   in the following table.
**
**   Paraffinic distillates   CAS No.           Oral LD50    API
**                            (g/kg)         Report No.
**   Solvent dewaxed, light
**   API 78-9           64742-56-9  >5       29-33104
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**   Solvent dewaxed, heavy
**   API 78-10*          64742-56-0  >5       29-33105
**   API 79-3            64742-65-0  >5       29-33067
**   API 79-4            64742-65-0  >5       29-33066
**   API 79-5            64742-65-0  >5       29-33068
**
**   White mineral oil
**   Tufflo 6056*                    >5       39-31651
**
**   Naphthenic distillates
**
**   Solvent refined, light
**   API 78-5            64741-97-5  >5       29-33106
**   Solvent refined, heavy
**   API 79-1            64741-96-4  >5       29-33065
**   Hydrotreated, heavy
**   API 83-15           64742-52-5  >5       33-32639
**
**
**
**   *      Although these materials are not included in the HPV  Lubricating
base
*    stocks category, they are similar to       other materials in the category
and
*    provide            supportive information.
F008 IUC31
F020 3752
EOR
F002 40
F010 5.1.2
F004 1
F005 ME
F006 A group of 5 male and 5 female rats were exposed for 4 hours
**   to an aerosol of the test material at a target concentration
**   of 5 mg/l.  Four additional groups of rats were then exposed
**   for 4 hours to target aerosol concentrations of 1, 1.5, 2
F007 A group of 5 male and 5 female rats were exposed for 4 hours
**   to an aerosol of the test material at a target concentration
**   of 5 mg/l.  Four additional groups of rats were then exposed
**   for 4 hours to target aerosol concentrations of 1, 1.5, 2.5
**   and 3.5 mg/l.  A control group exposed, in the chamber, to
**   air only was also included.
**   Animals were observed continuously during the first hour of
**   exposure, hourly for the remainder of the exposure and once
**   daily for the 14-day post exposure period.  Mortalities were
**   recorded and body weights were measured prior to exposure
**   and again 7 and 14 days after exposure.  On the 14th day
**   post-exposure, necropsies were performed on all surviving
**   animals. For all animals, including animals found dead, the
**   lungs and any other abnormal tissues were removed and fixed
**   for subsequent histopathological examination.
F008 IUC31
F020 3753
EOR
F002 40
F010 5.1.2
F004 1
```

F005 RE
F006 American Petroleum Institute (1987)
** Acute inhalation toxicity evaluation of a petroleum derived
** hydrocarbon in rats. API 83-12 Hydrotreated light naphthenic
** distillate CAS 64742-53-6
** API HESD Publ. 34-32775
F007 American Petroleum Institute (1987)
** Acute inhalation toxicity evaluation of a petroleum derived
** hydrocarbon in rats. API 83-12 Hydrotreated light naphthenic
** distillate CAS 64742-53-6
** API HESD Publ. 34-32775
F008 IUC4
F009 11-09-2010
F020 3754
EOR
F002 40
F010 5.1.2
F004 1
F005 RS
F006 Actual exposure concentrations and mortalities were as
** follows:
**
** Target level Actual concentration Mortality
** (mg/l) mg/l ±SD Male Female
** 0 0.02 0.01 0/5 0/5
** 1.0 1.04 0.1 1/5 1/5
** 1.5 1.51 0.15 0/5 0/5
** 2.5 2.37 0.31 3/5 3/5
** 3.5 3.
F007 Actual exposure concentrations and mortalities were as
** follows:
**
** Target level Actual concentration Mortality
** (mg/l) mg/l ±SD Male Female
** 0 0.02 0.01 0/5 0/5
** 1.0 1.04 0.1 1/5 1/5
** 1.5 1.51 0.15 0/5 0/5
** 2.5 2.37 0.31 3/5 3/5
** 3.5 3.49 0.36 5/5 5/5
** 5.0 5.05 0.18 5/5 5/5
**
** Particle size measurements confirmed that mass median
** aerodynamic diameter and geometric standard deviation values
** were in the ranges 1.7 to 2.5 mμ and 1.5 to 1.61
** respectively. These measurements confirm that the particles
** were within the respirable range.
** The LC50 for combined sexes was estimated to be 2.18 with
** 95% confidence limits of 1.80 to 2.55 mg/l.
**
** Body weight differences did not show a consistent dose
** related pattern.
**
** At the highest concentration, the animals were obscured by a
** dense aerosol and observations could not be made during the
** exposure period. In other groups, there was a decreased
** activity, wet inguinal area, eyes partially closed, wet
** coat, loose stool and oily coat during exposure.

** During the first week post-exposure, similar signs were
** observed as well as signs of poor condition, respiratory
** distress and some deaths occurred. During test week 2, most
** survivors were considered to be of normal appearance. The
** signs that were observed occurred in a dose related manner.
**
** At gross necropsy, dark red lungs were described for some
** animals. The incidence is shown below.
**

Dose group	Male	Female
0	0/5	0/5
1.0	1/5	1/5
1.5	0/5	0/5
2.5	3/5	3/5
3.5	5/5	5/5
5.0	5/5	5/5

**
** At histology, affected animals exhibited diffuse pulmonary
** congestion and perivascular edema that were mostly moderate
** or marked in degree. Less consistently spotty alveolar edema
** was also seen. There was widespread damage to alveolar walls
** resulting in fibronecrotic debris resembling hyaline
** membranes in more marked cases and extravasation of RBCs and
** PMNs. Necrosis and inflammation were seen in the walls of
** small blood vessels and there was spotty epithelial necrosis
** in small bronchioles, but the most severe damage seemed to
** be centroacinar. The larger airways were relatively
** unaffected.
**
** None of the surviving animals exhibited the above acute
** changes. However, most of the surviving animals exposed to
** 2.5 or 1.0 mg/l and above exhibited chronic inflammatory
** changes that were not seen in the controls and only
** occasionally in animals exposed at the 1.5 mg/l level, and
** then to a lesser degree of severity.
** Other findings were considered sporadic or unrelated to
** exposure to the test material.
F008 IUC31
F020 3755
EOR
F002 40
F010 5.1.2
F004 1
F005 TC
F006 Whole body exposures were carried out in stainless steel and
** glass chambers of 0.25 cubic meter volume.
** Aerosols were generated using a nebulizer.
** Concentrations of test material in the exposure chambers
** were determined gravimetrically by c
F007 Whole body exposures were carried out in stainless steel and
** glass chambers of 0.25 cubic meter volume.
** Aerosols were generated using a nebulizer.
** Concentrations of test material in the exposure chambers
** were determined gravimetrically by collection of the aerosol
** on filters. Analytical samples were taken at least once per
** hour during the exposure period. Particle size
** determinations were also carried out.

F008 IUC31
F020 3756
EOR
F002 40
F010 5.1.2
F004 2
F005 RE
F006 CONCAWE (1997)
** Lubricating oil basestocks
** Product dossier No. 97/108
** CONCAWE, Brussels
F007 CONCAWE (1997)
** Lubricating oil basestocks
** Product dossier No. 97/108
** CONCAWE, Brussels
F008 IUC31
F020 3757
EOR
F002 40
F010 5.1.2
F004 2
F005 RE
F006 Whitman, F. T., Freeman, J. J., Infurna, R. N. and Phillips,
** R. D. (1989)
** Evaluation of the acute and subacute inhalation toxicity of
** lubricating oil mists
** The toxicologist Vol. 9., p 143
F007 Whitman, F. T., Freeman, J. J., Infurna, R. N. and Phillips,
** R. D. (1989)
** Evaluation of the acute and subacute inhalation toxicity of
** lubricating oil mists
** The toxicologist Vol. 9., p 143
F008 IUC31
F020 3758
EOR
F002 40
F010 5.1.2
F004 2
F005 RM
F006 CONCAWE summarized the data available on the acute
** inhalation toxicity of lubricating oil mists in 4 hour
** exposure studies in rats.
** The data (Original source Whitman et al, 1989) on 3
** paraffinic distillates are shown in the following tabl
F007 CONCAWE summarized the data available on the acute
** inhalation toxicity of lubricating oil mists in 4 hour
** exposure studies in rats.
** The data (Original source Whitman et al, 1989) on 3
** paraffinic distillates are shown in the following table.
**
** Inhalation LC50
** (mg/l)
** Paraffinic distillates
** Solvent extracted, dewaxed >4
** Solvent extracted, dewaxed, hydrotreated >4
** Solvent dewaxed, light >4
F008 IUC31

F020 3759
EOR
F002 40
F010 5.1.3
F004 1
F005 ME
F006 Undiluted test material was applied as a single dose (2g/kg)
** to the shorn, abraded skin of 4 male and 4 female rabbits.
** The treated site was covered with an occlusive dressing for
** 24 hours. After removal of the dressing, the skin was wipe
F007 Undiluted test material was applied as a single dose (2g/kg)
** to the shorn, abraded skin of 4 male and 4 female rabbits.
** The treated site was covered with an occlusive dressing for
** 24 hours. After removal of the dressing, the skin was wiped
** with a wet towel to remove residual test material. The
** rabbits were observed for clinical signs and mortality
** hourly for the first 6 hours, then daily for dermal
** irritation and twice daily for clinical signs and mortality.
** Observation was carried out for a 14-day post treatment
** period. Body weights were recorded prior to administration
** of the test material, again 7 days post dosing and at study
** termination (14 days). At termination, all surviving animals
** were killed and subjected to a gross necropsy examination.
F008 IUC31
F020 3760
EOR
F002 40
F010 5.1.3
F004 1
F005 RE
F006 American Petroleum Institute (1986)
** Acute oral toxicity study in rats
** Acute dermal toxicity study in rabbits
** Primary dermal irritation study in rabbits
** Primary eye irritation study in rabbits
** Dermal sensitization study in Guinea pigs
** API 84
F007 American Petroleum Institute (1986)
** Acute oral toxicity study in rats
** Acute dermal toxicity study in rabbits
** Primary dermal irritation study in rabbits
** Primary eye irritation study in rabbits
** Dermal sensitization study in Guinea pigs
** API 84-01 Light paraffinic distillate CAS 64741-50-0
** API Med. Res. Publ.: 33-30595
F008 IUC4
F009 11-09-2010
F020 3761
EOR
F002 40
F010 5.1.3
F004 1
F005 RS
F006 There were no mortalities during the study.
** With the exception of skin irritation, there were no
** clinical signs of toxicity except that on day 4 soft stool
** was observed in 1 male and 3 female animals.

```
**   Dermal irritation ranged from slight to
F007 There were no mortalities during the study.
**   With the exception of skin irritation, there were no
**   clinical signs of toxicity except that on day 4 soft stool
**   was observed in 1 male and 3 female animals.
**   Dermal irritation ranged from slight to severe for erythema
**   and edema, from slight to marked for fissuring and slight to
**   moderate for atonia and desquamation.  Slight coriaceousness
**   was also observed.
**   Body weight losses were recorded for 2 male and 3 female
**   animals at day 7.  One male was less than starting weight on
**   both day 7 and day 14.
F008 IUC31
F020 3762
EOR
F002 40
F010 5.1.3
F004 2
F005 ME
F006 Undiluted test material was applied as a single dose (2g/kg)
**   to the shorn, abraded skin of 4 male and 4 female rabbits.
**   The treated site was covered with an occlusive dressing for
**   24 hours.  After dressing removal, the skin was wiped with
F007 Undiluted test material was applied as a single dose (2g/kg)
**   to the shorn, abraded skin of 4 male and 4 female rabbits.
**   The treated site was covered with an occlusive dressing for
**   24 hours.  After dressing removal, the skin was wiped with a
**   wet towel to remove residual test material.  The rabbits
**   were observed for clinical signs and mortality hourly for
**   the first 6 hours, then daily for dermal irritation and
**   twice daily for clinical signs and mortality. Observation
**   was carried out for a 14-day post treatment period.  Body
**   weights were recorded prior to administration of the test
**   material, again 7 days post dosing and at study termination
**   (14 days). At termination, all surviving animals were killed
**   and subjected to a gross necropsy examination.
F008 IUC31
F020 3763
EOR
F002 40
F010 5.1.3
F004 2
F005 RE
F006 American Petroleum Institute (1986)
**   Acute oral toxicity study in rats
**   Acute dermal toxicity study in rabbits
**   Primary dermal irritation study in rabbits
**   Primary eye irritation study in rabbits
**   Dermal sensitization study in Guinea pigs
**   API 83
F007 American Petroleum Institute (1986)
**   Acute oral toxicity study in rats
**   Acute dermal toxicity study in rabbits
**   Primary dermal irritation study in rabbits
**   Primary eye irritation study in rabbits
**   Dermal sensitization study in Guinea pigs
**   API 83-12 Hydrotreated light naphthenic distillate CAS
```

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**   64742-53-6
**   API Med. Res. Publ.: 33-30592
F008 IUC4
F009 11-09-2010
F020 3764
EOR
F002 40
F010 5.1.3
F004 2
F005 RS
F006 There were no deaths during the study.
**   The only clinical observation with the exception of skin
**   irritation was soft stool in all animals. This was observed
**   3 hours after dosing and returned to normal by day 2.
**   Skin irritation was observed i
F007 There were no deaths during the study.
**   The only clinical observation with the exception of skin
**   irritation was soft stool in all animals. This was observed
**   3 hours after dosing and returned to normal by day 2.
**   Skin irritation was observed in all animals and ranged from
**   slight to severe for erythema and edema, from slight to
**   marked for atonia, desquamation and fissuring and from
**   slight to moderate for coriaceousness. Other dermal
**   irritation seen included blanching and subcutaneous
**   hemorrhage.
**   All animals had gained weight by the end of the study.
**   At necropsy, except for the skin lesions no other visible
**   lesions were recorded.
F008 IUC31
F020 3765
EOR
F002 40
F010 5.1.3
F004 3
F005 RE
F006 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 78-10 paraffinic oil (150
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33105
F007 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 78-10 paraffinic oil (150
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33105
F008 IUC31
F020 3766
EOR
F002 40
F010 5.1.3
F004 3
F005 RE
F006 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 78-5 naphthenic oil (150
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33106
F007 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 78-5 naphthenic oil (150
**   SUS/100 °F)
```

```
**   API Med. Res. Publ. 29-33106
F008 IUC31
F020 3767
EOR
F002 40
F010 5.1.3
F004 3
F005 RE
F006 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 78-9 paraffinic oil (70
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33104
F007 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 78-9 paraffinic oil (70
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33104
F008 IUC31
F020 3768
EOR
F002 40
F010 5.1.3
F004 3
F005 RE
F006 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 79-1 naphthenic oil (90
**   SUS/210 °F)
**   API Med. Res. Publ. 29-33065
F007 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 79-1 naphthenic oil (90
**   SUS/210 °F)
**   API Med. Res. Publ. 29-33065
F008 IUC31
F020 3769
EOR
F002 40
F010 5.1.3
F004 3
F005 RE
F006 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 79-3 paraffinic oil (350
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33067
F007 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 79-3 paraffinic oil (350
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33067
F008 IUC31
F020 3770
EOR
F002 40
F010 5.1.3
F004 3
F005 RE
F006 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 79-4 paraffinic oil (550
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33066
```

F007 American Petroleum Institute (1982)
** Acute toxicity tests of API sample 79-4 paraffinic oil (550
** SUS/100 °F)
** API Med. Res. Publ. 29-33066
F008 IUC31
F020 3771
EOR
F002 40
F010 5.1.3
F004 3
F005 RE
F006 American Petroleum Institute (1982)
** Acute toxicity tests of API sample 79-5 paraffinic oil (800
** SUS/100 °F)
** API Med. Res. Publ. 29-33068
F007 American Petroleum Institute (1982)
** Acute toxicity tests of API sample 79-5 paraffinic oil (800
** SUS/100 °F)
** API Med. Res. Publ. 29-33068
F008 IUC31
F020 3772
EOR
F002 40
F010 5.1.3
F004 3
F005 RE
F006 American Petroleum Institute (1986)
** Acute oral toxicity study in rats
** Acute dermal toxicity study in rabbits
** Primary dermal irritation study in rabbits
** Primary eye irritation study in rabbits
** Dermal sensitization study in guinea pigs
** API sa
F007 American Petroleum Institute (1986)
** Acute oral toxicity study in rats
** Acute dermal toxicity study in rabbits
** Primary dermal irritation study in rabbits
** Primary eye irritation study in rabbits
** Dermal sensitization study in guinea pigs
** API sample 83-15 hydrotreated heavy naphthenic distillate
** (CAS 64742-52-5)
** API Health Environ. Sci. Dep. Rep. 33-32639
F008 IUC31
F020 3773
EOR
F002 40
F010 5.1.3
F004 3
F005 RE
F006 CONCAWE (1997)
** Lubricating oil basestocks
** Product dossier No. 97/108
** CONCAWE, Brussels
F007 CONCAWE (1997)
** Lubricating oil basestocks
** Product dossier No. 97/108
** CONCAWE, Brussels

F008 IUC31
F020 3774
EOR
F002 40
F010 5.1.3
F004 3
F005 RM
F006 CONCAWE summarized the data available on the acute dermal
** toxicity of lubricating oil base stocks in rabbits. The
** data are shown in the following table.
**
** Paraffinic distillates
F007 CONCAWE summarized the data available on the acute dermal
** toxicity of lubricating oil base stocks in rabbits. The
** data are shown in the following table.
**
** Paraffinic distillates
**
** Solvent dewaxed, light
** API 78-9
** Solvent dewaxed, heavy
** API 78-10*
** API 79-3
** API 79-4
** API 79-5
**
** Naphthenic distillates
**
** Solvent refined, light
** API 78-5
** Solvent refined, heavy
** API 79-1
** Hydrotreated, heavy
** API 83-15
**
** * Although this material is not included in the HPV Lubricating base
* stocks category, it is similar to other materials in the category and
* provides supportive information.
F008 IUC31
F020 3775
EOR
F002 40
F010 5.11
F004 1
F005 ME
F006 Groups of 10 presumed-pregnant rats were distributed into
** the
** following groups:
**
** Group Dose level Gestation days of
** (mg/kg/day) administration
**

Dermal LD50 (g/kg)	API Report No.	CAS No.
64742-56-9 >5	29-33104	
64742-56-0 >5	29-33105	
64742-65-0 >5	29-33067	
64742-65-0 >5	29-33066	
64742-65-0 >5	29-33068	
64741-97-5 >5	29-33106	
64741-96-4 >5	29-33065	
64742-52-5 >2	33-32639	

```
**     1    0 (remote control)      0-19
**     2    0 (proximate control)   0-19
**
F007 Groups of 10 presumed-pregnant rats were distributed into
**   the
**   following groups:
**
**     Group       Dose level           Gestation days of
**             (mg/kg/day)          administration
**
**     1    0 (remote control)      0-19
**     2    0 (proximate control)   0-19
**     3     30                      0-19
**     4     125                     0-19
**     5     500                     0-19
**     6    1000                    0-19
**     7*    500 (bioavailability)  10-12
**
**   * Group size was 5 at start but increased to 8 after study
**   initiation.
**
**   The test material was applied daily to the shorn dorsal skin
**   at the dose levels shown above and for the duration
**   indicated. The rats were fitted with collars to prevent oral
**   ingestion of the applied material.
**    Since it was believed that inhalation of test material
**   could be a confounding factor a second group of controls
**   (remote controls) were housed in an area in which they could
**   not inhale gasoil that had been applied to other animals.
**
**   Observations were made daily for clinical signs and body
**   weights and food consumption were recorded regularly
**   throughout the study.
**
**   Each female was sacrificed on day 20 of presumed gestation
**   and the thoracic and abdominal cavities were examined
**   grossly.
**   The thymus and liver were removed from each animal and
**   weighed and then preserved in formalin but not examined
**   further.
**   The uterus and ovaries were removed and examined grossly.
**   The number of corpora lutea per ovary for each rat was
**   recorded. The ovaries of non-pregnant females were examined
**   and then discarded. Uterus weights were also determined.
**   The uterine contents of each pregnant rat were exposed and a
**   record made of the number and location of all implantations.
**   At necropsy, blood samples were taken from all the animals
**   and a range of clinical chemical measurements were made.
**   Fetuses were examined and half were preserved for
**   examination of soft tissue abnormalities, the remainder
**   being differentially stained for skeletal examination.
F008 IUC31
F020 3776
EOR
F002 40
F010 5.11
F004 1
```

F005 RE
F006 Mobil (undated)
** Developmental toxicity screen in rats exposed dermally to
** heavy vacuum gas oil (HVGO)
** Study No. 61801 Final report
F007 Mobil (undated)
** Developmental toxicity screen in rats exposed dermally to
** heavy vacuum gas oil (HVGO)
** Study No. 61801 Final report
F008 IUC31
F020 3777
EOR
F002 40
F010 5.11
F004 1
F005 RL
F006 The report evaluated was incomplete but nevertheless was
** sufficient to identify the relevant effects of exposure to
** the test material.
F007 The report evaluated was incomplete but nevertheless was
** sufficient to identify the relevant effects of exposure to
** the test material.
F008 IUC31
F020 3778
EOR
F002 40
F010 5.11
F004 1
F005 RS
F006 Parental animals.
**
** There were no clinical signs attributable to exposure to
** HVGO other than in the highest dose group in which 2 rats
** had a red vaginal discharge, one animal was pale in color
** and six had decreased stool. The latter observat
F007 Parental animals.
**
** There were no clinical signs attributable to exposure to
** HVGO other than in the highest dose group in which 2 rats
** had a red vaginal discharge, one animal was pale in color
** and six had decreased stool. The latter observation was
** probably associated with a smaller food consumption in this
** group. Although food consumption was generally also less
** than controls in the 500 mg/kg/day group there was no
** associated body weight decrease.
** At doses in excess of 125 mg/kg/day there was a decrease in
** mean body weights which reflected the decreased litter sizes
** for this group.
** The only dose-related finding at gross necropsy was a pale
** appearance of lungs in a few animals. 4 animals were
** affected at the highest dose and only one in the 500
** mg/kg/day group.
** Mean thymus weights of animals in the highest dose group
** were approximately half those of the control groups.
** Although absolute liver weights were unaffected by exposure
** to HVGO, mean relative liver weights were increased
** (approximately 15%) in groups exposed to doses greater than

** 125 mg/kg/day.
**
** Observations of Dams at Caesarean section.
**
** Parameters with treatment-related effects are shown below.
**
** Dose group (mg/kg/day)
**
** 0(R) 0(P) 30 125 500 1000
** Pregnant females
** 9 10 10 8 10 9
** Dams with viable fetuses
** 9 10 10 8 10 6
** Dams with all resorptions
** 0 0 0 0 0 3
** Mean litter size of viable fetuses
** 13.9 14 13.8 14.4 10 5.8
** Resorptions
** Mean 1.1 0.6 1.1 1.1 5.6 9.9
** % Dams with resorptions
** 56 50 70 63 100 100
**
** Parameters unaffected were:
** No. premature births
** Female mortality
** No. corporea lutea
** No. implantation sites
** Pre-implantation losses
** Viable male fetuses
** Viable female fetuses
** No. dead fetuses
**
**
** Fetal evaluations
**
** fetal body weights were significantly reduced in fetuses
** exposed in utero to HVGO at doses in excess of 125
** mg/kg/day.
** Although there were differences between control and treated
** crown-rump lengths they were not statistically significant.
** At the time of external examination, malformations were
** observed in one fetus in the 1000 mg/kg/day group. The
** fetus was edematous and pale in color. Both hindpaws were
** malformed; the digits were reduced in size with a
** subcutaneous hematoma located at the distal most aspect of
** each of the digits.
** Malformations of the vertebral column were restricted to the
** 500 mg/kg/day group.
** Although a variety of skeletal malformations were observed
** in treated and control groups the degree of aberant
** development in control fetuses was not as severe as in the
** HVGO-exposed groups.
** Visceral malformations were restricted to two fetuses in the
** 500 mg/kg/day group. One fetus had microphthalmia and the
** other fetus had a diaphragmatic hernia which displaced the
** heart from the left to right hand side.
F008 IUC31

F020 3779
EOR
F002 40
F010 5.11
F004 1
F005 TS
F006 Heavy vacuum gasoil CAS 64741-57-7
F007 Heavy vacuum gasoil CAS 64741-57-7
F008 IUC31
F020 3780
EOR
F002 40
F010 5.11
F004 2
F005 RM
F006 Heavy vacuum gas oil is used as a starting material for base
** oil production. As such, it can be considered a "worst case"
** example of the unrefined/mildly refined base oil
** subcategory. Studies on this material are summarized below.
F007 Heavy vacuum gas oil is used as a starting material for base
** oil production. As such, it can be considered a "worst case"
** example of the unrefined/mildly refined base oil
** subcategory. Studies on this material are summarized below.
F008 IUC31
F020 3781
EOR
F002 40
F010 5.11
F004 3
F005 ME
F006 Undiluted heavy vacuum gas oil was applied at doses of 0,
** 30, 125, 500 and 2000 mg/kg/day to the shorn skin of groups
** of ten male and ten female Sprague Dawley rats. The material
** was applied 5 days each week for 13 weeks. Collars were
** fitte
F007 Undiluted heavy vacuum gas oil was applied at doses of 0,
** 30, 125, 500 and 2000 mg/kg/day to the shorn skin of groups
** of ten male and ten female Sprague Dawley rats. The material
** was applied 5 days each week for 13 weeks. Collars were
** fitted to the animals to prevent oral ingestion.
** Body weights were recorded weekly throughout the study and
** clinical observations were made daily. Skin irritation was
** assessed weekly. At 5 and 13 weeks blood samples were taken
** for hematological and clinical chemical analyses. At the end
** of the study (13 weeks) all surviving animals were
** sacrificed and a gross necropsy examination was performed.
** 20 tissues were preserved for subsequent histopathological
** examination.
F008 IUC31
F020 3782
EOR
F002 40
F010 5.11
F004 3
F005 RE
F006 Mobil (1988)
** Thirteen-week dermal administration of heavy vacuum gas oil

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**   to rats.
**   Study No. 61590
**   Mobil Environmental and Health Science Laboratory
F007 Mobil (1988)
**   Thirteen-week dermal administration of heavy vacuum gas oil
**   to rats.
**   Study No. 61590
**   Mobil Environmental and Health Science Laboratory
F008 IUC31
F020 3783
EOR
F002 40
F010 5.11
F004 3
F005 RL
F006 The report evaluated was incomplete but nevertheless was
**   sufficient to identify the relevant effects of exposure to
**   the test material.
F007 The report evaluated was incomplete but nevertheless was
**   sufficient to identify the relevant effects of exposure to
**   the test material.
F008 IUC31
F020 3784
EOR
F002 40
F010 5.11
F004 3
F005 RS
F006 Two males and one female in the high dose group died during
**   the study. The male deaths were considered to be compound
**   related but the female death was considered incidental.
**   Growth rates of males and females in the highest dose group
**   were r
F007 Two males and one female in the high dose group died during
**   the study. The male deaths were considered to be compound
**   related but the female death was considered incidental.
**   Growth rates of males and females in the highest dose group
**   were reduced compared to controls. At 13 weeks the males
**   weighed 20% less and the females 15% less than controls.
**   At 2000 mg/kg/day males and females had reduced erythrocytes
**   and reduced platelets at 5 and 13 weeks. Similar effects
**   were also found in the 500 mg/kg/day females.
**
**   Clinical chemical changes in males and females at 2000
**   mg/kg/day consisted of:
**    twofold increase in sorbitol dehydrogenase
**    twofold increase in cholesterol
**    50% reduction in uric acid
**   In addition in females at 500 mg/kg/day, glucose was reduced
**   and in the 500 mg/kg males cholesterol was increased.
**
**   At gross necropsy, relative thymus weights were reduced in
**   the 500 (by 25%) and 2000 mg/kg/day (by 50%) animals of both
**   sexes. Relative liver weights were also increased at 500 and
**   2000 mg/kg/day for both sexes.
**
**   Histological examination revealed decreased erythropoeisis
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**   and fibrosis of the bone marrow in the 2000 mg/kg/day males.
**   There was a reduction in thymic lymphocytes in the
**   2000 mg/kg/day groups (marked for males and moderate for
**   females) and a slight reduction in the 500 mg/kg/day groups
**   for both sexes.
**
**   No effects were found on either sperm morphology or in the
**   results of the urinalysis.
**
**   The NOEL for both males and females was found to be 125
**   mg/kg/day.
F008 IUC31
F020 3785
EOR
F002 40
F010 5.2.1
F004 1
F005 ME
F006 0.5 ml of undiluted test material was applied to the shorn
**   dorsal skin in two areas on each of 6 male rabbits. One area
**   was intact and the other abraded skin. The treated area was
**   then covered with an occlusive dressing.
**   After 24 hours, the
F007 0.5 ml of undiluted test material was applied to the shorn
**   dorsal skin in two areas on each of 6 male rabbits. One area
**   was intact and the other abraded skin. The treated area was
**   then covered with an occlusive dressing.
**   After 24 hours, the dressing was removed and the treated
**   skin
**   was wiped to remove any residue of test material. The degree
**   of erythema and edema was recorded according to the Draize
**   scale. A second reading of skin responses was made at 72
**   hours and again at 96 hours, 7 and 14 days. Results of the
**   24 and 72-hour readings were used to determine the Primary
**   Irritation Index.
F008 IUC31
F020 3786
EOR
F002 40
F010 5.2.1
F004 1
F005 RE
F006 American Petroleum Institute (1986)
**   Acute oral toxicity study in rats
**   Acute dermal toxicity study in rabbits
**   Primary dermal irritation study in rabbits
**   Primary eye irritation study in rabbits
**   Dermal sensitization study in Guinea pigs
**   API 84
F007 American Petroleum Institute (1986)
**   Acute oral toxicity study in rats
**   Acute dermal toxicity study in rabbits
**   Primary dermal irritation study in rabbits
**   Primary eye irritation study in rabbits
**   Dermal sensitization study in Guinea pigs
**   API 84-01 Light paraffinic distillate CAS 64741-50-0
**   API Med. Res. Publ.: 33-30595
```

F008 IUC4
F009 11-09-2010
F020 3787
EOR
F002 40
F010 5.2.1
F004 1
F005 RS
F006 One animal died on day 10 even though there had been no
** signs of ill health previously. Irritation scores given
** below are averages from 5 animals.
**

** Observation period	Erythema Intact	Edema Abraded	Average Intact	Average Abraded	Score
** 24 h					

F007 One animal died on day 10 even though there had been no
** signs of ill health previously. Irritation scores given
** below are averages from 5 animals.
**

** Observation period	Erythema Intact	Edema Abraded	Average Intact	Average Abraded	Score
** 24 hrs.	2.3	2.5	2.3	2.3	4.8
** 72 hrs.	1.8	2.0	1.7	2.0	3.8
** 96 hrs.	1.5	1.7	1.0	1.0	2.6
** 7 days	0.3	0.3	0.3	0.5	0.8
** 14 days	0	0	0	0	0

**
** Primary dermal irritation index: 4.3
F008 IUC31
F020 3788
EOR
F002 40
F010 5.2.1
F004 2
F005 ME
F006 0.5 ml of undiluted test material was applied to the shorn
** skin in two areas on each of 6 male rabbits. One area was
** intact and the other abraded skin. The treated area was then
** covered with an occlusive dressing.
** After 24 hours, the dressi
F007 0.5 ml of undiluted test material was applied to the shorn
** skin in two areas on each of 6 male rabbits. One area was
** intact and the other abraded skin. The treated area was then
** covered with an occlusive dressing.
** After 24 hours, the dressing was removed and the treated
** skin
** was wiped to remove any residue of test material. The degree
** of erythema and edema was recorded according to the Draize
** scale. A second reading of skin responses was made at 72
** hours and again at 96 hours, 7 and 14 days. Results of the
** 24 and 72-hour readings were used to determine the Primary
** Irritation Index.
F008 IUC31
F020 3789
EOR

F002 40
F010 5.2.1
F004 2
F005 RE
F006 American Petroleum Institute (1986)
** Acute oral toxicity study in rats
** Acute dermal toxicity study in rabbits
** Primary dermal irritation study in rabbits
** Primary eye irritation study in rabbits
** Dermal sensitization study in Guinea pigs
** API 83
F007 American Petroleum Institute (1986)
** Acute oral toxicity study in rats
** Acute dermal toxicity study in rabbits
** Primary dermal irritation study in rabbits
** Primary eye irritation study in rabbits
** Dermal sensitization study in Guinea pigs
** API 83-12 Hydrotreated light naphthenic distillate CAS
** 64742-53-6
** API Med. Res. Publ.: 33-30592
F008 IUC4
F009 11-09-2010
F020 3790
EOR
F002 40
F010 5.2.1
F004 2
F005 RS
F006 Average Irritation scores are given below:
**

** Observation period	Erythema Intact		Edema Abraded		Average Intact	Abraded	Score
** 24 hrs.		2.3	2.3	2.7	2.7	5.0	
** 72 hrs.		3.0	3.0	2.5	3.0	5.8	
** 96 hrs.		2.7	2.8	2.7	3.0	5.6	
** 7 days	1.3	2.2	0				

F007 Average Irritation scores are given below:
**

** Observation period	Erythema Intact		Edema Abraded		Average Intact	Abraded	Score
** 24 hrs.		2.3	2.3	2.7	2.7	5.0	
** 72 hrs.		3.0	3.0	2.5	3.0	5.8	
** 96 hrs.		2.7	2.8	2.7	3.0	5.6	
** 7 days	1.3	2.2	0.8	1.7	3.0		
** 14 days		0	0	0	0	0	

**
** Primary dermal irritation index: 5.4
F008 IUC31
F020 3791
EOR
F002 40
F010 5.2.1
F004 3
F005 RE
F006 American Petroleum Institute (1982)

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**   Acute toxicity tests of API sample 78-10 paraffinic oil (150
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33105
F007 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 78-10 paraffinic oil (150
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33105
F008 IUC31
F020 3792
EOR
F002 40
F010 5.2.1
F004 3
F005 RE
F006 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 78-5 naphthenic oil (150
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33106
F007 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 78-5 naphthenic oil (150
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33106
F008 IUC31
F020 3793
EOR
F002 40
F010 5.2.1
F004 3
F005 RE
F006 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 78-9 paraffinic oil (70
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33104
F007 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 78-9 paraffinic oil (70
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33104
F008 IUC31
F020 3794
EOR
F002 40
F010 5.2.1
F004 3
F005 RE
F006 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 79-1 naphthenic oil (90
**   SUS/210 °F)
**   API Med. Res. Publ. 29-33065
F007 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 79-1 naphthenic oil (90
**   SUS/210 °F)
**   API Med. Res. Publ. 29-33065
F008 IUC31
F020 3795
EOR
F002 40
F010 5.2.1
```

F004 3
F005 RE
F006 American Petroleum Institute (1982)
** Acute toxicity tests of API sample 79-3 paraffinic oil (350
** SUS/100 °F)
** API Med. Res. Publ. 29-33067
F007 American Petroleum Institute (1982)
** Acute toxicity tests of API sample 79-3 paraffinic oil (350
** SUS/100 °F)
** API Med. Res. Publ. 29-33067
F008 IUC31
F020 3796
EOR
F002 40
F010 5.2.1
F004 3
F005 RE
F006 American Petroleum Institute (1982)
** Acute toxicity tests of API sample 79-4 paraffinic oil (550
** SUS/100 °F)
** API Med. Res. Publ. 29-33066
F007 American Petroleum Institute (1982)
** Acute toxicity tests of API sample 79-4 paraffinic oil (550
** SUS/100 °F)
** API Med. Res. Publ. 29-33066
F008 IUC31
F020 3797
EOR
F002 40
F010 5.2.1
F004 3
F005 RE
F006 American Petroleum Institute (1982)
** Acute toxicity tests of API sample 79-5 paraffinic oil (800
** SUS/100 °F)
** API Med. Res. Publ. 29-33068
F007 American Petroleum Institute (1982)
** Acute toxicity tests of API sample 79-5 paraffinic oil (800
** SUS/100 °F)
** API Med. Res. Publ. 29-33068
F008 IUC31
F020 3798
EOR
F002 40
F010 5.2.1
F004 3
F005 RE
F006 American Petroleum Institute (1986)
** Acute oral toxicity study in rats
** Acute dermal toxicity study in rabbits
** Primary dermal irritation study in rabbits
** Primary eye irritation study in rabbits
** Dermal sensitization study in guinea pigs
** API sa
F007 American Petroleum Institute (1986)
** Acute oral toxicity study in rats
** Acute dermal toxicity study in rabbits

```
**   Primary dermal irritation study in rabbits
**   Primary eye irritation study in rabbits
**   Dermal sensitization study in guinea pigs
**   API sample 83-15 hydrotreated heavy naphthenic distillate
**   (CAS 64742-52-5)
**   API Health Environ. Sci. Dep. Rep. 33-32639
F008 IUC31
F020 3799
EOR
F002 40
F010 5.2.1
F004 3
F005 RE
F006 CONCAWE (1997)
**   Lubricating oil basestocks
**   Product dossier No. 97/108
**   CONCAWE, Brussels
F007 CONCAWE (1997)
**   Lubricating oil basestocks
**   Product dossier No. 97/108
**   CONCAWE, Brussels
F008 IUC31
F020 3800
EOR
F002 40
F010 5.2.1
F004 3
F005 RM
F006 CONCAWE summarized the data available on skin irritation for
**   the lubricating oil base stocks.  The data are shown in the
**   following table.
**
**
**   Paraffinic distillates   Irritation* API Report
**
**   Solvent dewaxed, light
**   API 78-9 (64
F007 CONCAWE summarized the data available on skin irritation for
**   the lubricating oil base stocks.  The data are shown in the
**   following table.
**
**
**   Paraffinic distillates   Irritation* API Report
**
**   Solvent dewaxed, light
**   API 78-9 (64742-56-9)    Slight (0.6)      29-33104
**   Solvent dewaxed, heavy
**   API 78-10*** (64742-56-0)      Non  (0.27) 29-33105
**   API 79-3     (64742-65-0)      Non  (0.33) 29-33067
**   API 79-4     (64742-65-0)      Non  (0.34) 29-33066
**   API 79-5     (64742-65-0)      Non  (0.38) 29-33068
**
**   White mineral oil***     Slight            Hoekstra & Phillips
**
**   Naphthenic distillates
**
**   Solvent refined, light
```

```
**   API 78-5  (64741-97-5)   Slight  (0.65)    29-33106
**   Solvent refined, heavy
**   API 79-1  (64741-96-4)   Slight  (0.8)     29-33065
**   Hydrotreated, heavy
**   API 83-15  (64742-52-5)  Slight (1.3)**    33-32639
**
**
**
**   *      NB Irritation described as slight, moderate or
**    non-irritating in the original reports (Mean          irritation score
given in
*    parentheses)
**
**   **     Irritation index
**
**   ***    Although these materials are not included in the HPV  Lubricating
*    base stocks category, they are similar to  other materials in the
*    category and provide           supportive information.
F008 IUC31
F020 3801
EOR
F002 40
F010 5.2.2
F004 1
F005 ME
F006 0.1 ml of undiluted test material was applied to the corneal
**   surface of one eye of each of 9 rabbits, the other eye was
**   untreated and served as control.
**   After 20 to 30 seconds, the treated eyes of 3 rabbits were
**   washed with lukewarm water f
F007 0.1 ml of undiluted test material was applied to the corneal
**   surface of one eye of each of 9 rabbits, the other eye was
**   untreated and served as control.
**   After 20 to 30 seconds, the treated eyes of 3 rabbits were
**   washed with lukewarm water for 1 minute. Eyes of the other 6
**   rabbits were not washed.
**   Readings of ocular lesions for all animals were made at 1,
**   24, 48, 72 hours and 7 days after treatment. Sodium
**   fluorescein was used to aid in revealing possible corneal
**   injury.
F008 IUC31
F020 3802
EOR
F002 40
F010 5.2.2
F004 1
F005 RE
F006 American Petroleum Institute (1986)
**   Acute oral toxicity study in rats
**   Acute dermal toxicity study in rabbits
**   Primary dermal irritation study in rabbits
**   Primary eye irritation study in rabbits
**   Dermal sensitization study in Guinea pigs
**   API 84
F007 American Petroleum Institute (1986)
**   Acute oral toxicity study in rats
**   Acute dermal toxicity study in rabbits
```

**   Primary dermal irritation study in rabbits
**   Primary eye irritation study in rabbits
**   Dermal sensitization study in Guinea pigs
**   API 84-01 Light paraffinic distillate CAS 64741-50-0
**   API Med. Res. Publ.: 33-30595
F008 IUC4
F009 11-09-2010
F020 3803
EOR
F002 40
F010 5.2.2
F004 1
F005 RS
F006 One animal died on day 7 but this was not considered to be
**   treatment related.
**   The test material did not cause a pain response, corneal or
**   iridial irritation. The eye irritation that occurred had
**   cleared by 48 hours.
**   The primary eye irritati
F007 One animal died on day 7 but this was not considered to be
**   treatment related.
**   The test material did not cause a pain response, corneal or
**   iridial irritation. The eye irritation that occurred had
**   cleared by 48 hours.
**   The primary eye irritation scores (according to the standard
**   Draize scoring procedure) were as follows:
**
**   Period   Unwashed   Washed
**   eyes   eyes
**   1 hour   3.0   4.0
**   24 hours   1.7   0
**   Scores of 0 were recorded at all other observation times.
F008 IUC31
F020 3804
EOR
F002 40
F010 5.2.2
F004 2
F005 ME
F006 0.1 ml of undiluted test material was applied to the corneal
**   surface of one eye of each of 9 rabbits, the other eye was
**   untreated and served as control.
**   After 20 to 30 seconds, the treated eyes of 3 rabbits were
**   washed with lukewarm water f
F007 0.1 ml of undiluted test material was applied to the corneal
**   surface of one eye of each of 9 rabbits, the other eye was
**   untreated and served as control.
**   After 20 to 30 seconds, the treated eyes of 3 rabbits were
**   washed with lukewarm water for 1 minute. Eyes of the other 6
**   rabbits were not washed.
**   Readings of ocular lesions for all animals were made at 1,
**   24, 48, 72 hours and 7 days after treatment. Sodium
**   fluorescein was used to aid in revealing possible corneal
**   injury.
F008 IUC31
F020 3805
EOR

F002 40
F010 5.2.2
F004 2
F005 RE
F006 American Petroleum Institute (1986)
** Acute oral toxicity study in rats
** Acute dermal toxicity study in rabbits
** Primary dermal irritation study in rabbits
** Primary eye irritation study in rabbits
** Dermal sensitization study in Guinea pigs
** API 83
F007 American Petroleum Institute (1986)
** Acute oral toxicity study in rats
** Acute dermal toxicity study in rabbits
** Primary dermal irritation study in rabbits
** Primary eye irritation study in rabbits
** Dermal sensitization study in Guinea pigs
** API 83-12 Hydrotreated light naphthenic distillate CAS
** 64742-53-6
** API Med. Res. Publ.: 33-30592
F008 IUC4
F009 11-09-2010
F020 3806
EOR
F002 40
F010 5.2.2
F004 2
F005 RS
F006 There was no pain response during instillation of the test
** material and no corneal or iridial irritation was seen
** during the study.
** Any irritation that occurred had cleared by 48 hours.
** The primary eye irritation scores for the first 48 hou
F007 There was no pain response during instillation of the test
** material and no corneal or iridial irritation was seen
** during the study.
** Any irritation that occurred had cleared by 48 hours.
** The primary eye irritation scores for the first 48 hours of
** the study were as follows:
** Period Unwashed Washed
** eyes eyes
** 1 hour 2.7 2.0
** 24 hours 0.3 0
** 48 hours 0 0
F008 IUC31
F020 3807
EOR
F002 40
F010 5.2.2
F004 3
F005 RE
F006 American Petroleum Institute (1982)
** Acute toxicity tests of API sample 78-10 paraffinic oil (150
** SUS/100 °F)
** API Med. Res. Publ. 29-33105
F007 American Petroleum Institute (1982)
** Acute toxicity tests of API sample 78-10 paraffinic oil (150

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**   SUS/100 °F)
**   API Med. Res. Publ. 29-33105
F008 IUC31
F020 3808
EOR
F002 40
F010 5.2.2
F004 3
F005 RE
F006 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 78-5 naphthenic oil (150
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33106
F007 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 78-5 naphthenic oil (150
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33106
F008 IUC31
F020 3809
EOR
F002 40
F010 5.2.2
F004 3
F005 RE
F006 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 78-9 paraffinic oil (70
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33104
F007 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 78-9 paraffinic oil (70
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33104
F008 IUC31
F020 3810
EOR
F002 40
F010 5.2.2
F004 3
F005 RE
F006 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 79-1 naphthenic oil (90
**   SUS/210 °F)
**   API Med. Res. Publ. 29-33065
F007 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 79-1 naphthenic oil (90
**   SUS/210 °F)
**   API Med. Res. Publ. 29-33065
F008 IUC31
F020 3811
EOR
F002 40
F010 5.2.2
F004 3
F005 RE
F006 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 79-3 paraffinic oil (350
**   SUS/100 °F)
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**   API Med. Res. Publ. 29-33067
F007 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 79-3 paraffinic oil (350
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33067
F008 IUC31
F020 3812
EOR
F002 40
F010 5.2.2
F004 3
F005 RE
F006 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 79-4 paraffinic oil (550
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33066
F007 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 79-4 paraffinic oil (550
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33066
F008 IUC31
F020 3813
EOR
F002 40
F010 5.2.2
F004 3
F005 RE
F006 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 79-5 paraffinic oil (800
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33068
F007 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 79-5 paraffinic oil (800
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33068
F008 IUC31
F020 3814
EOR
F002 40
F010 5.2.2
F004 3
F005 RE
F006 American Petroleum Institute (1986)
**   Acute oral toxicity study in rats
**   Acute dermal toxicity study in rabbits
**   Primary dermal irritation study in rabbits
**   Primary eye irritation study in rabbits
**   Dermal sensitization study in guinea pigs
**   API sa
F007 American Petroleum Institute (1986)
**   Acute oral toxicity study in rats
**   Acute dermal toxicity study in rabbits
**   Primary dermal irritation study in rabbits
**   Primary eye irritation study in rabbits
**   Dermal sensitization study in guinea pigs
**   API sample 83-15 hydrotreated heavy naphthenic distillate
**   (CAS 64742-52-5)
```

```
**   API Health Environ. Sci. Dep. Rep. 33-32639
F008 IUC31
F020 3815
EOR
F002 40
F010 5.2.2
F004 3
F005 RE
F006 Carpenter, C. P. and Smythe, H. F. (1946)
**   Chemical burns of the rabbit cornea
**   Am. J. Ophthal. Vol. 29, pp 1363-1372
F007 Carpenter, C. P. and Smythe, H. F. (1946)
**   Chemical burns of the rabbit cornea
**   Am. J. Ophthal. Vol. 29, pp 1363-1372
F008 IUC31
F020 3816
EOR
F002 40
F010 5.2.2
F004 3
F005 RE
F006 CONCAWE (1997)
**   Lubricating oil basestocks
**   Product dossier No. 97/108
**   CONCAWE, Brussels
F007 CONCAWE (1997)
**   Lubricating oil basestocks
**   Product dossier No. 97/108
**   CONCAWE, Brussels
F008 IUC31
F020 3817
EOR
F002 40
F010 5.2.2
F004 3
F005 RM
F006 CONCAWE summarized the data available on eye irritation for
**   the lubricating oil base stocks.  The data are shown in the
**   following table.
**
**   Paraffinic distillates   Irritation* API report No.
**   Solvent dewaxed, light
**   API 78-9      (64742-56-9)     S
F007 CONCAWE summarized the data available on eye irritation for
**   the lubricating oil base stocks.  The data are shown in the
**   following table.
**
**   Paraffinic distillates   Irritation* API report No.
**   Solvent dewaxed, light
**   API 78-9      (64742-56-9)     Slight            29-33104
**   Solvent dewaxed, heavy
**   API 78-10**  (64742=56-0)      Non         29-33105
**   API 79-3      (64742-65-0)     Non         29-33067
**   API 79-4      (64742-65-0)     Non         29-33066
**   API 79-5      (64742-65-0)     Non         29-33068
**
**   Naphthenic distillates
```

```
**
**   Solvent refined, light
**   API 78-5      (64741-97-5)     Non         29-33106
**   Solvent refined, heavy
**   API 79-1      (64741-96-4)     Non         29-33065
**   Hydrotreated, heavy
**   API 83-15     (64742-52-5)     Slight            33-32639
**
**   Other mineral oils
**
**   Paraffin oil**                 Slight          Carpenter & Smyth
**
**   *      Irritation described as slight, moderate or
**    non-irritating
**
**   **     Although these materials are not included in the HPV  Lubricating
base
*    stocks category, they are similar to       other materials in the category
*    and provide        supportive information.
F008 IUC31
F020 3818
EOR
F002 40
F010 5.3
F004 1
F005 ME
F006 0.4 ml of a 25% mixture of test material and paraffin oil
**   was applied under an occlusive dressing to the shorn skin of
**   10 male and 10 female animals. 6 hours after application the
**   dressings were removed and the skin wiped to remove residue
F007 0.4 ml of a 25% mixture of test material and paraffin oil
**   was applied under an occlusive dressing to the shorn skin of
**   10 male and 10 female animals. 6 hours after application the
**   dressings were removed and the skin wiped to remove residues
**   of test material. The animals received one application each
**   week for 3 weeks. The same application site was used each
**   time. 2 weeks following the third application, a challenge
**   dose (0.4 ml of a 1% mixture in paraffin oil) was applied
**   in the same manner as the sensitizing doses. A previously
**   untreated site was used for the challenge application.
**   The application sites for sensitizing and challenge doses
**   were read for erythema and edema 24 and 48 hours after patch
**   removal. To assist in the reading of the response to the
**   final challenge dose the test site was depilated 3 hours
**   prior to reading by using a commercially available
**   depilatory cream.
**
**   Positive control (2,4-dinitrochlorobenzene at 0.3% in 80%
**   aqueous ethanol), vehicle control and naive control groups
**   were included in this study and the procedure for these was
**   the same as for the test groups.
F008 IUC31
F020 3819
EOR
F002 40
F010 5.3
F004 1
```

F005 RE
F006 American Petroleum Institute (1986)
** Acute oral toxicity study in rats
** Acute dermal toxicity study in rabbits
** Primary dermal irritation study in rabbits
** Primary eye irritation study in rabbits
** Dermal sensitization study in Guinea pigs
** API 84
F007 American Petroleum Institute (1986)
** Acute oral toxicity study in rats
** Acute dermal toxicity study in rabbits
** Primary dermal irritation study in rabbits
** Primary eye irritation study in rabbits
** Dermal sensitization study in Guinea pigs
** API 84-01 Light paraffinic distillate CAS 64741-50-0
** API Med. Res. Publ.: 33-30595
F008 IUC4
F009 11-09-2010
F020 3820
EOR
F002 40
F010 5.3
F004 1
F005 RS
F006 The criteria used to evaluate the responses are described in
** the report as follows:
** Determination of sensitization was based upon reactions to
** the challenge dose. Grades of 1 or greater in the test
** animals indicate evidence of sensitization
F007 The criteria used to evaluate the responses are described in
** the report as follows:
** Determination of sensitization was based upon reactions to
** the challenge dose. Grades of 1 or greater in the test
** animals indicate evidence of sensitization, provided grades
** of less than 1 are seen in the naive controls. If grades of
** 1 or greater are noted in the naive control animals, then
** the reactions of test animals that exceed the most severe
** naive control reaction are considered sensitization
** reactions.
**
** Using these criteria, none of the test animals became
** sensitized following treatment with API 84-01. In contrast,
** all the positive control animals were sensitized by their
** treatment.
F008 IUC31
F020 3821
EOR
F002 40
F010 5.3
F004 2
F005 ME
F006 0.4 ml of a 50% mixture of test material and paraffin oil
** was applied under an occlusive dressing to the shorn skin of
** 10 male and 10 female animals. 6 hours after application,
** the
** dressings were removed and the skin wiped to remove residu
F007 0.4 ml of a 50% mixture of test material and paraffin oil

```
**   was applied under an occlusive dressing to the shorn skin of
**   10 male and 10 female animals. 6 hours after application,
**   the
**   dressings were removed and the skin wiped to remove residues
**   of test material. The animals received one application each
**   week for 3 weeks. The same application site was used each
**   time. 2 weeks following the third application, a challenge
**   dose (0.4 ml of a 1% mixture in paraffin oil) was applied
**   in the same manner as the sensitizing doses. A previously
**   untreated site was used for the challenge application.
**   The application sites for sensitizing and challenge doses
**   were read for erythema and edema 24 and 48 hours after patch
**   removal. To assist in the reading of the response to the
**   final challenge dose the test site was depilated 3 hours
**   prior to reading by using a commercially available
**   depilatory cream.
**
**   Positive control (2,4-dinitrochlorobenzene at 0.3% in 80%
**   aqueous ethanol), vehicle control and naive control groups
**   were included in this study and the procedure for these was
**   the same as for the test groups.
F008 IUC31
F020 3822
EOR
F002 40
F010 5.3
F004 2
F005 RE
F006 American Petroleum Institute (1986)
**   Acute oral toxicity study in rats
**   Acute dermal toxicity study in rabbits
**   Primary dermal irritation study in rabbits
**   Primary eye irritation study in rabbits
**   Dermal sensitization study in Guinea pigs
**   API 83
F007 American Petroleum Institute (1986)
**   Acute oral toxicity study in rats
**   Acute dermal toxicity study in rabbits
**   Primary dermal irritation study in rabbits
**   Primary eye irritation study in rabbits
**   Dermal sensitization study in Guinea pigs
**   API 83-12 Hydrotreated light naphthenic distillate CAS
**   64742-53-6
**   API Med. Res. Publ.: 33-30592
F008 IUC4
F009 11-09-2010
F020 3823
EOR
F002 40
F010 5.3
F004 2
F005 RS
F006 The criteria used to evaluate the responses are described in
**   the report as follows:
**   Determination of sensitization was based upon reactions to
**   the challenge dose. Grades of 1 or greater in the test
**   animals indicate evidence of sensitization
```

F007 The criteria used to evaluate the responses are described in
**   the report as follows:
**   Determination of sensitization was based upon reactions to
**   the challenge dose. Grades of 1 or greater in the test
**   animals indicate evidence of sensitization, provided grades
**   of less than 1 are seen in the naive controls. If grades of
**   1 or greater are noted in the naive control animals, then
**   the reactions of test animals that exceed the most severe
**   naive control reaction are considered sensitization
**   reactions.
**
**   One animal had a score of 0.5 after challenge with API
**   83-12. In contrast, all the positive control animals were
**   sensitized by their treatment. The sample of API 83-12 was
**   therefore non sensitizing.
F008 IUC31
F020 3824
EOR
F002 40
F010 5.3
F004 3
F005 RE
F006 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 78-10 paraffinic oil (150
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33105
F007 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 78-10 paraffinic oil (150
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33105
F008 IUC31
F020 3825
EOR
F002 40
F010 5.3
F004 3
F005 RE
F006 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 78-5 naphthenic oil (150
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33106
F007 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 78-5 naphthenic oil (150
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33106
F008 IUC31
F020 3826
EOR
F002 40
F010 5.3
F004 3
F005 RE
F006 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 78-9 paraffinic oil (70
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33104
F007 American Petroleum Institute (1982)

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**   Acute toxicity tests of API sample 78-9 paraffinic oil (70
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33104
F008 IUC31
F020 3827
EOR
F002 40
F010 5.3
F004 3
F005 RE
F006 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 79-1 naphthenic oil (90
**   SUS/210 °F)
**   API Med. Res. Publ. 29-33065
F007 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 79-1 naphthenic oil (90
**   SUS/210 °F)
**   API Med. Res. Publ. 29-33065
F008 IUC31
F020 3828
EOR
F002 40
F010 5.3
F004 3
F005 RE
F006 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 79-3 paraffinic oil (350
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33067
F007 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 79-3 paraffinic oil (350
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33067
F008 IUC31
F020 3829
EOR
F002 40
F010 5.3
F004 3
F005 RE
F006 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 79-4 paraffinic oil (550
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33066
F007 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 79-4 paraffinic oil (550
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33066
F008 IUC31
F020 3830
EOR
F002 40
F010 5.3
F004 3
F005 RE
F006 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 79-5 paraffinic oil (800
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**   SUS/100 °F)
**   API Med. Res. Publ. 29-33068
F007 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 79-5 paraffinic oil (800
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33068
F008 IUC31
F020 3831
EOR
F002 40
F010 5.3
F004 3
F005 RE
F006 American Petroleum Institute (1986)
**   Acute oral toxicity study in rats
**   Acute dermal toxicity study in rabbits
**   Primary dermal irritation study in rabbits
**   Primary eye irritation study in rabbits
**   Dermal sensitization study in guinea pigs
**   API sa
F007 American Petroleum Institute (1986)
**   Acute oral toxicity study in rats
**   Acute dermal toxicity study in rabbits
**   Primary dermal irritation study in rabbits
**   Primary eye irritation study in rabbits
**   Dermal sensitization study in guinea pigs
**   API sample 83-15 hydrotreated heavy naphthenic distillate
**   (CAS 64742-52-5)
**   API Health Environ. Sci. Dep. Rep. 33-32639
F008 IUC31
F020 3832
EOR
F002 40
F010 5.3
F004 3
F005 RE
F006 CONCAWE (1997)
**   Lubricating oil basestocks
**   Product dossier No. 97/108
**   CONCAWE, Brussels
F007 CONCAWE (1997)
**   Lubricating oil basestocks
**   Product dossier No. 97/108
**   CONCAWE, Brussels
F008 IUC31
F020 3833
EOR
F002 40
F010 5.3
F004 3
F005 RM
F006 CONCAWE summarized the data available on skin sensitization
**   for the lubricating oil basestocks.  The methods and
**   criteria used were the same as those described in the
**   previous two robust summaries. The data are shown in the
**   following table.
F007 CONCAWE summarized the data available on skin sensitization
```

```
**   for the lubricating oil basestocks.  The methods and
**   criteria used were the same as those described in the
**   previous two robust summaries. The data are shown in the
**   following table.
**
**   Paraffinic distillates         Sensitization     API Report
**   Solvent dewaxed, light
**   API 78-9     64742-56-9  Non         29-33104
**   Solvent dewaxed, heavy
**   API 78-10*   64742-56-0  Non         29-33105
**   API 79-3     64742-65-0  Non         29-33067
**   API 79-4     64742-65-0  Non         29-33066
**   API 79-5     64742-65-0  Non         29-33068
**
**   Naphthenic distillates
**
**   Solvent refined, light
**   API 78-5     64741-97-5  Non         29-33106
**   Solvent refined, heavy
**   API 79-1     64741-96-4  Non         29-33065
**   Hydrotreated, heavy
**   API 83-15    64742-52-5  Non         33-32639
**
**   *      Although this material is not included in the HPV     Lubricating
base
*    stocks category, it is similar to    other materials in the category and
*    provides           supportive information.
F008 IUC31
F020 3834
EOR
F002 40
F010 5.4
F004 2
F005 ME
F006 Undiluted API 83-12 was applied at doses of 200, 1000 and
**   2000 mg/kg/day to the shorn dorsal skin of groups of five
**   male and five female rabbits. The test material was applied
**   to the skin 3 times each week for 4 weeks (12 applications
**   total
F007 Undiluted API 83-12 was applied at doses of 200, 1000 and
**   2000 mg/kg/day to the shorn dorsal skin of groups of five
**   male and five female rabbits. The test material was applied
**   to the skin 3 times each week for 4 weeks (12 applications
**   total).  The applied material was covered with an occlusive
**   dressing for 6 hours, which was then removed and the skin
**   was
**   wiped with a dry gauze to remove any residual material. A
**   group of five rabbits of each sex served as sham controls.
**   The test skin site of each animal was examined and scored
**   for irritation prior to each application of test material.
**   Mortality and moribundity checks were performed twice daily
**   and body weights were recorded weekly.
**   At termination, blood samples were taken for a range of
**   hematological and clinical chemical measurements. Urine
**   samples were also collected and frozen for possible future
**   examination.
**   A complete gross necropsy was performed on all animals.
```

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**   Major organs were weighed and tissues were processed for
**   subsequent histopathological examination.
F008 IUC31
F020 3835
EOR
F002 40
F010 5.4
F004 2
F005 RE
F006 American Petroleum Institute (1986)
**   28 day dermal toxicity study in the rabbit
**   API 83-12 Hydrotreated light naphthenic distillate CAS
**   64742-53-6
**
**   API Med. Res. Publ. 33-30499
F007 American Petroleum Institute (1986)
**   28 day dermal toxicity study in the rabbit
**   API 83-12 Hydrotreated light naphthenic distillate CAS
**   64742-53-6
**
**   API Med. Res. Publ. 33-30499
F008 IUC4
F009 11-09-2010
F020 3836
EOR
F002 40
F010 5.4
F004 2
F005 RS
F006 No deaths occurred during the study.
**   Skin irritation occurred to varying degrees in all animals
**   treated with API 83-12.  There was moderate irritation in
**   the high dose males and females. In the mid dose
**   group moderate irritation occurred in
F007 No deaths occurred during the study.
**   Skin irritation occurred to varying degrees in all animals
**   treated with API 83-12.  There was moderate irritation in
**   the high dose males and females. In the mid dose
**   group moderate irritation occurred in the females and slight
**   irritation in the males.  In the low dose group minimal
**   irritation occurred in both sexes.  The overall mean
**   irritation scores were:
**
**   Dose level   Males Females
**    (mg/kg)
**   Control 0    0     0
**   200          0.1   0.4
**   1000         2.0   2.2
**   2000         2.6   3.1
**
**   Soft stool was also observed in several animals but this
**   also occurred in a control male was not considered to be
**   dose related.  All high dose females appeared thin and this
**   was considered to be treatment related.
**   Body weight gains were reduced in the high dose males and
**   females and in the mid dose females when compared to
**   their respective controls.
```

** Overall weight changes (kg) are shown in the following table
**
** Dose level Males Females
** (mg/kg)
** Control 0 +0.5 +0.3
** 200 +0.3 +0.4
** 1000 +0.3 0.0*
** 2000 +0.1* -0.2*
**
** * statistically significant (p </= 0.05)
**
** Clinical chemical and hematological values were considered
** to be unaffected by treatment. A low value (cf control) for
** white cell count in the low dose female group was considered
** incidental since the value was within a normal range and was
** not a dose-related effect.
**
** Although there were some organ weight differences, they were
** considered incidental to treatment. The exception was for
** the absolute testis weights, which were lower in the high
** dose males and the relative weights of the right testis
** which were also lower than controls.
**
** At gross necropsy, findings for the skin consisted of dry,
** scaly, rough, fissured, crusted and/or thickened skin. This
** was a common finding in all treatment groups.
**
** Histopathological examination revealed slight to moderate
** proliferative changes in the skin in all rabbits in the
** high dose group. These changes were accompanied by an
** increased granulopoeisis of the bone marrow. The testes of
** 3 of the 5 males in the high dose group had bilateral
** diffuse tubular hypoplasia accompanied by aspermatogenesis
** and atrophy of the accessory sex organs. There were no
** changes observed in either the testes or epididymes of the
** male rabbits in the mid or low dose groups.
** No other treatment-related histopathological changes were
** recorded.
F008 IUC31
F020 3837
EOR
F002 40
F010 5.4
F004 3
F005 ME
F006 Three related, but separate studies were carried out at the
** same time on 6 different food grade white oils and 3 food
** grade waxes.
** Only the information on the oils is included here. The
** information on waxes is included in the Waxes and Rela
F007 Three related, but separate studies were carried out at the
** same time on 6 different food grade white oils and 3 food
** grade waxes.
** Only the information on the oils is included here. The
** information on waxes is included in the Waxes and Related
** Materials HPV Test Plan.
**

** In the main study, groups of 20 male and 20 female rats were
** fed diets containing one of 6 different white oils at
** dietary
** concentrations of 0.002, 0.02, 0.2 and 2.0% for 90 days.
** Further groups of 60 male and 60 females were fed untreated
** control diet. Additionally groups of 20 rats of each sex
** were fed diets containing 2.0% coconut oil.
**
** The second study was a reversibility study. Groups of 10
** rats of each sex were fed diets for 90 days containing one
** of the 6 different oils at the 2.0% level or coconut oil at
** 2%. These animals were then fed control diet for 28 days
** following the 90-days treatment. Groups of 30 rats of each
** sex served as controls for this reversibility study.
**
** A third study was designed to determine tissue levels of
** hydrocarbons. In this study, 5 rats of each sex were fed
** diets
** containing one of the 6 oils or coconut oil at the 2.0%
** dietary level for 90 days. Extra groups of rats (5 of each
** sex) were fed control diet or coconut oil or one of the
** six oils for 90 days followed by exposure to control diet
** only for a further 28 days.
**
** In all three studies, animals were monitored for weight,
** food intakes and clinical condition throughout. An
** ophthalmic examination was performed prior to treatment and
** prior to necropsy on the animals in the main study and those
** for the study of reversibility.
** A full necropsy was performed on the main and reversibility
** study animals and a full range of hematological parameters
** were measured on blood samples taken from the animals.
** Clinical chemical measurements were also made on serum
** separated from the blood samples. A selection of organs was
** weighed and a range of tissues retained for subsequent
** histopathological examination. All tissues from the high
** dose group and control groups were examined by light
** microscopy. Additionally the liver, lymph nodes, spleen,
** kidney, small intestine and lung were examined from all the
** intermediate dose groups.
** Mineral hydrocarbon levels were measured in a limited number
** of tissues in those animals designated for tissue level
** determinations.
F008 IUC31
F020 3838
EOR
F002 40
F010 5.4
F004 3
F005 RE
F006 BIBRA (1992)
** A 90-day feeding study in the rat with six different mineral
** oils (N15(H), N70(H), N70(A), P15(H), N10(A) and P100(H),
** three different mineral waxes (a low melting point wax, a
** high melting point wax and a high sulphur wax) and
F007 BIBRA (1992)
** A 90-day feeding study in the rat with six different mineral

```
**   oils (N15(H), N70(H), N70(A), P15(H), N10(A) and P100(H),
**   three different mineral waxes (a low melting point wax, a
**   high melting point wax and a high sulphur wax) and coconut
**   oil.
**   BIBRA project No. 3.1010
F008 IUC31
F020 3839
EOR
F002 40
F010 5.4
F004 3
F005 RE
F006 Firriolo, J. M., Morris, C. F., Trimmer, G. W., Twitty, L.
**   D., Smith, J. H. and Freeman, J. J. (1995)
**   Comparative 90-day feeding study with low-viscosity white
**   mineral oil in Fischer-344 and Sprague-Dawley-derived CRL:CD
**   rats.
**   Toxicologic P
F007 Firriolo, J. M., Morris, C. F., Trimmer, G. W., Twitty, L.
**   D., Smith, J. H. and Freeman, J. J. (1995)
**   Comparative 90-day feeding study with low-viscosity white
**   mineral oil in Fischer-344 and Sprague-Dawley-derived CRL:CD
**   rats.
**   Toxicologic Pathology Vol 23, No. 1, pages 26-33
F008 IUC4
F009 11-09-2010
F020 3840
EOR
F002 40
F010 5.4
F004 3
F005 RE
F006 McKee, R. H., Plutnick, R. T. and Traul, K. A. (1987)
**   Assessment of the potential reproductive and subchronic
**   toxicity of EDS coal liquids in Sprague-Dawley rats.
**   Toxicology Vol 46, pp 267-280
F007 McKee, R. H., Plutnick, R. T. and Traul, K. A. (1987)
**   Assessment of the potential reproductive and subchronic
**   toxicity of EDS coal liquids in Sprague-Dawley rats.
**   Toxicology Vol 46, pp 267-280
F008 IUC31
F009 23-09-2001
F020 3841
EOR
F002 40
F010 5.4
F004 3
F005 RM
F006 While only one report (three studies) is described here,
**   numerous repeat dose studies on white oils destined for use
**   in foods have been conducted and reported in the open
**   literature.
**
**   Recent studies with a low molecular weight white oil h
F007 While only one report (three studies) is described here,
**   numerous repeat dose studies on white oils destined for use
**   in foods have been conducted and reported in the open
```

```
**   literature.
**
**   Recent studies with a low molecular weight white oil have
**   demonstrated that the F 344 rat is more sensitive in its
**   response to mineral hydrocarbons than the Sprague Dawley rat
**   (Firriolo et al). Indeed other studies on white oils with
**   Sprague Dawley rats (McKee et al) and beagle dogs (Bird et
**   al) have also not resulted in any reported effects .
F008 IUC31
F020 3842
EOR
F002 40
F010 5.4
F004 3
F005 RS
F006 The six oils tested had average molecular weights ranging
**   from 320 to 510. The effects observed in the study were
**   inversely related to the oil's molecular weight. Thus the
**   oil with the lowest molecular weight caused the most  severe
**   effects
F007 The six oils tested had average molecular weights ranging
**   from 320 to 510. The effects observed in the study were
**   inversely related to the oil's molecular weight. Thus the
**   oil with the lowest molecular weight caused the most  severe
**   effects and at lower dose levels than the higher molecular
**   weight materials. For simplicity, only the results of the
**   highest and lowest molecular weight oils are summarized
**   below. Furthermore, the results of the reversibility study
**   are not given in detail here.
**   In general, there was evidence of reversibility of the
**   effects but reversibility was not complete for all of the
**   parameters measured.
**
**   P 100 H  (Average molecular weight 510)
**
**   There were no treatment-related clinical signs, nor was
**   there an effect on body weight. Food consumption was
**   increased in the males of the highest dose group but this
**   was less than 10% greater than for the controls. Ophthalmic
**   examination did not reveal any effects. Organ weights,
**   hematology and clinical chemistry were unaffected except for
**   a 10% increase in ASAT in the males in the highest dose
**   group.
**   There were no treatment-related findings at necropsy and the
**   histological examination did not reveal any
**   treatment-related effects.
**   A small amount of mineral hydrocarbon was found in the
**   livers of the male rats in the highest dose group.
**
**
**   N 10 A  (Average molecular weight 320)
**
**   There were no treatment-related clinical signs, nor was
**   there an effect on body weight. Food consumption was
**   increased in the males of the highest dose group but this
**   was less than 10% greater than for the controls. Ophthalmic
**   examination did not reveal any effects.
```

**

** Organ weights

**

** Increases in organ weights are as shown below, other organ
** weights were unaffected.

**

** Increases (%) at
** Organ Dietary concentration

**

** Males Females
** 0.2% 2.0% 0.2% 2.0%
** Kidney (abs.) 4 6 5
** (rel.) 7 7
** Liver (abs) 8 11 6 21
** (rel.) 6 12 8 23
** Spleen (abs.) 17
** (rel.) 5 19
** MLN* (abs.) 224 220
** (rel.) 224 226

**

** * NB Mesenteric Lymph Node weights only determined for
** the 2% dose group in the reversal group of animals and not
** for the main study animals.

**

** Hematology

**

** In the males in the highest dose group there were increases
** in Neutrophils (41%), monocytes (28%) and basophils (200%)
** In the females, changes occurred in the 2% and 0.2% dose
** groups. These were as follows:

**

** Change (% + or -)
** at dose level
** 0.2% 2%

**

** RBC - 2 - 3
** Hemoglobin - 2 - 3
** WBC + 23
** Differential WBC
** Neutrophils + 75
** Monocytes + 51
** Eosinophils + 38

**

** Clinical chemistry

**

** In the males there was a reduction in Alkaline phosphatase
** of
** 8 and 2% in the 2 and 0.2% dose groups respectively.
** Changes in clinical chemical parameters in the females were
** as follows:

**

** Change (% + or -)
** at dose level
** 0.2% 2%
** ALKP - 12 - 13
** ASAT + 12
** Gamma GT + 91

**
** Histopathology
**
** Liver
** Liver lesions comprised mirogranuloma or granuloma, the
** distinction between being purely related to size. Lesions
** were classified as microgranuloma if the average diameter
** was less than 25% of the average hepatic lobule. The
** histological features of the two were similar and consisted
** of collections of macrophages, some with necrotic cells
** surrounded by inflammatory cells and variable fibrosis.
**
** No lesions were observed in the males whereas granulomas
** were seen in the females in the highest dose group.
** In females in the recovery group 28 days after cessation of
** exposure, the incidence was unchanged but the severity of
** the lesions had decreased.
**
** Mesenteric Lymph node
**
** The lymph node lesions comprised focal collections of
** macrophages, often in the cortical region. The macrophages
** were lightly vacuolated, giving a slightly foamy appearance
** to their cytoplasm. Some macrophages had a yellowish-brown
** pigmentation of varied intensity. The focal collections of
** macrophages were classified as histiocytosis and were scored
** as minimal, mild, moderate or marked based on size and
** abundance. The foci of histiocytosis were not homogeneously
** distributed; they were often restricted to one node or even
** to part of one node.
** Histiocytosis was also found in control rats but was
** generally restricted to isolated foci and was always
** classified as minimal.
** Compared to controls, in males histiocytosis increased down
** to the 0.2% dose group. In the females, histiocytosis was
** also observed in the 0.02% dose group.
** In the reversibility group the severity and incidence was
** reduced after being fed control diet for 28 days.
**
** Ileum and jejunum
**
** There was a significant increase in vacuolation of the
** lamina propria in the high dose female group.
**
**
** In summary, the NOELs and LOELs for the six oils that were
** tested are as follows.
**
**

** Oil	LOEL (histiocytosis) Dietary concentration	NOAEL
** N10A	0.02%	
** N15H	0.002%	
** P15H	0.02%	
** N70A	0.02%	

```
**    N70H        0.02%
**    P100H       -           2.0%
F008 IUC31
F020 3843
EOR
F002 40
F010 5.4
F004 3
F005 TS
F006 Six white oils examined in this study were characterized.
**   Only the average molecular weight and viscosity at 100 °C
**   are shown below:
**
**   Sample       Viscosity   Average
**             (cSt)           Molecular
**                        Weight
**
**   N10(A)       3.08        320
**   N15(H)       3.45        330
**   P15(H)       3.5
F007 Six white oils examined in this study were characterized.
**   Only the average molecular weight and viscosity at 100 °C
**   are shown below:
**
**   Sample       Viscosity   Average
**             (cSt)           Molecular
**                        Weight
**
**   N10(A)       3.08        320
**   N15(H)       3.45        330
**   P15(H)       3.52        350
**   N70(A)       7.88        410
**   N70(H)       7.65        420
**   P100(H)            11          510
F008 IUC31
F020 3844
EOR
F002 40
F010 5.4
F004 4
F005 AD
F006 Summary of dermal repeat dose studies.doc
F007 Summary of dermal repeat dose studies.doc
F020 3856
F021 Summary of dermal repeat dose studies
F022 39936
F023 13:2:2003 17:40
F024 doc
EOR
F002 40
F010 5.4
F004 4
F005 RE
F006 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 78-10 paraffinic oil (150
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33105
```

F007 American Petroleum Institute (1982)
** Acute toxicity tests of API sample 78-10 paraffinic oil (150
** SUS/100 °F)
** API Med. Res. Publ. 29-33105
F008 IUC31
F020 3845
EOR
F002 40
F010 5.4
F004 4
F005 RE
F006 American Petroleum Institute (1982)
** Acute toxicity tests of API sample 78-5 naphthenic oil (150
** SUS/100 °F)
** API Med. Res. Publ. 29-33106
F007 American Petroleum Institute (1982)
** Acute toxicity tests of API sample 78-5 naphthenic oil (150
** SUS/100 °F)
** API Med. Res. Publ. 29-33106
F008 IUC31
F020 3846
EOR
F002 40
F010 5.4
F004 4
F005 RE
F006 American Petroleum Institute (1982)
** Acute toxicity tests of API sample 78-9 paraffinic oil (70
** SUS/100 °F)
** API Med. Res. Publ. 29-33104
F007 American Petroleum Institute (1982)
** Acute toxicity tests of API sample 78-9 paraffinic oil (70
** SUS/100 °F)
** API Med. Res. Publ. 29-33104
F008 IUC31
F020 3847
EOR
F002 40
F010 5.4
F004 4
F005 RE
F006 American Petroleum Institute (1982)
** Acute toxicity tests of API sample 79-1 naphthenic oil (90
** SUS/210 °F)
** API Med. Res. Publ. 29-33065
F007 American Petroleum Institute (1982)
** Acute toxicity tests of API sample 79-1 naphthenic oil (90
** SUS/210 °F)
** API Med. Res. Publ. 29-33065
F008 IUC31
F020 3848
EOR
F002 40
F010 5.4
F004 4
F005 RE
F006 American Petroleum Institute (1982)

```
**   Acute toxicity tests of API sample 79-3 paraffinic oil (350
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33067
F007 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 79-3 paraffinic oil (350
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33067
F008 IUC31
F020 3849
EOR
F002 40
F010 5.4
F004 4
F005 RE
F006 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 79-4 paraffinic oil (550
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33066
F007 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 79-4 paraffinic oil (550
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33066
F008 IUC31
F020 3850
EOR
F002 40
F010 5.4
F004 4
F005 RE
F006 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 79-5 paraffinic oil (800
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33068
F007 American Petroleum Institute (1982)
**   Acute toxicity tests of API sample 79-5 paraffinic oil (800
**   SUS/100 °F)
**   API Med. Res. Publ. 29-33068
F008 IUC31
F020 3851
EOR
F002 40
F010 5.4
F004 4
F005 RE
F006 American Petroleum Institute (1987)
**   28-Day dermal toxicity study in the rabbit.
**   API sample 83-15 hydrotreated heavy naphthenic distillate
**   (CAS 64742-52-5)
**   API Helath Environ. Sci. Dep. Rep. 35-32430
F007 American Petroleum Institute (1987)
**   28-Day dermal toxicity study in the rabbit.
**   API sample 83-15 hydrotreated heavy naphthenic distillate
**   (CAS 64742-52-5)
**   API Helath Environ. Sci. Dep. Rep. 35-32430
F008 IUC31
F020 3852
EOR
```

F002 40
F010 5.4
F004 4
F005 RE
F006 CONCAWE (1997)
** Lubricating oil basestocks
** Product dossier No. 97/108
** CONCAWE, Brussels
F007 CONCAWE (1997)
** Lubricating oil basestocks
** Product dossier No. 97/108
** CONCAWE, Brussels
F008 IUC31
F020 3853
EOR
F002 40
F010 5.4
F004 4
F005 RE
F006 Trimmer, G. W. et al (1989)
** Evaluation of the dermal toxicity of paraffinic lube oils
** Toxicologist Vol 9, pp 162
F007 Trimmer, G. W. et al (1989)
** Evaluation of the dermal toxicity of paraffinic lube oils
** Toxicologist Vol 9, pp 162
F008 IUC31
F020 3854
EOR
F002 40
F010 5.4
F004 4
F005 RM
F006 Data on repeated dose dermal studies in rabbits have been
** summarized elsewhere (CONCAWE 1997).
** The attached tabulated summary of information is taken from
** the CONCAWE publication.
F007 Data on repeated dose dermal studies in rabbits have been
** summarized elsewhere (CONCAWE 1997).
** The attached tabulated summary of information is taken from
** the CONCAWE publication.
F008 IUC31
F020 3855
EOR
F002 40
F010 5.4
F004 5
F005 ME
F006 Undiluted API 84-01 was applied at doses of 200, 1000 and
** 2000 mg/kg/day to the shorn dorsal skin of groups of five
** male and five female rabbits. The test material was applied
** to the skin 3 times each week for 4 weeks (12 applications
** tota
F007 Undiluted API 84-01 was applied at doses of 200, 1000 and
** 2000 mg/kg/day to the shorn dorsal skin of groups of five
** male and five female rabbits. The test material was applied
** to the skin 3 times each week for 4 weeks (12 applications
** total). The applied material was covered with an occlusive

```
**   dressing for 6 hours, which was then removed and the skin
**   was
**   wiped with a dry gauze to remove any residual material.  A
**   group of five rabbits of each sex served as sham controls.
**   The test skin site of each animal was examined and scored
**   for irritation prior to each application of test material.
**   Mortality and moribundity checks were performed twice daily
**   and body weights were recorded weekly.  At termination,
**   blood samples were taken for a range of hematological and
**   clinical chemical measurements.  Urine samples were also
**   collected and frozen for possible future examination.  A
**   complete gross necropsy was performed on all animals.  Major
**   organs were weighed and tissues were processed for
**   subsequent histopathological examination.
F008 IUC31
F020 3857
EOR
F002 40
F010 5.4
F004 5
F005 RE
F006 American Petroleum Institute (1986)
**   28 day dermal toxicity study in the rabbit
**   API 84-01 Light paraffinic distillate CAS 64741-50-0
**   API Med. Res. Publ. 33-31642
F007 American Petroleum Institute (1986)
**   28 day dermal toxicity study in the rabbit
**   API 84-01 Light paraffinic distillate CAS 64741-50-0
**   API Med. Res. Publ. 33-31642
F008 IUC4
F009 11-09-2010
F020 3858
EOR
F002 40
F010 5.4
F004 5
F005 RS
F006 Three animals died during the study but these were not
**   dose-related and were, therefore, considered unrelated to
**   treatment.  Sporadic clinical signs were also unrelated to
**   treatment.
**   In the high dose group, body weight gains were affected b
F007 Three animals died during the study but these were not
**   dose-related and were, therefore, considered unrelated to
**   treatment.  Sporadic clinical signs were also unrelated to
**   treatment.
**   In the high dose group, body weight gains were affected by
**   treatment. In the females, there was a group net loss in
**   weight whereas in the males the gains were significantly
**   less than controls. These effects were largely due to
**   effects on growth rate during the first week of the study.
**   A mean irritation index was calculated for each group each
**   day and also for each treatment group overall.  The value
**   was determined from Draize scores for erythema and edema for
**   each animal.  The mean irritation scores for each group
**   were:
**   Group              Irritation                                  score
```

** Control (male) 0
** Control (female) 0
** 200 mg/kg (male) 0.5
** 200 mg/kg (female) 0.4
** 1000 mg/kg (male) 1.7
** 1000 mg/kg (female) 2.0
** 2000 mg/kg (male) 3.1
** 2000 mg/kg (female) 3.2
**
** There were no statistical differences between treated and
** control groups for any of the hematological determinations.
** These were: Total red blood cells, total white blood cells,
** hemoglobin concentration and hematocrit %.
**
** The clinical chemical data for the treated and control males
** was similar. In the females, there was a reduced BUN and an
** increased SGPT for the low dose females. Since no other
** differences were noted and that values were within normal
** limits the effects were not considered to be toxicologically
** significant. The clinical chemical measurements consisted
** of: glucose, BUN, SGOT, SGPT, ALP and total protein.
**
** The following absolute and relative organ weight differences
** (compared to controls) were recorded.
**
** 2000 mg/kg
**
	Males	Females
Relative liver wt.	Increased	Increased
Relative kidney wt.	Increased	Increased
Relative pituitary wt.	Increased	
Relative left testis wt.	Decreased	
Relative brain wt.		Increased

**
** 1000 mg/kg
**
Abs. Rt. kidney wt.	Decreased	
Abs. Heart wt.		Decreased

**
** None of the organ weight differences were considered
** treatment-related. The higher than control relative organ
** weights were considered as a function of the reduced body
** weights in the affected animals.
**
** The only findings at gross necropsy were confined to the
** treated skin. These consisted of dry, scaly, rough, and/or
** reddened skin and thickened dermis. These findings were
** noted throughout the treatment groups. There were no
** treatment-related gross necropsy findings in the internal
** organs.
**
** Microscopic pathology findings were also largely confined to
** the skin. Slight to moderate proliferative changes of the
** skin were present in all of the male and female rabbits in
** the highest dose group.
**
** The testes of one of the five males in the high dose group
** had bilateral diffuse tubular hypoplasia accompanied by

```
**   aspermatogenesis and hypoplasia of the epididymis.  These
**   changes were considered to represent immature testes.
**   Similar changes were not seen in the other animals in this
**   dose group.
F008 IUC31
F020 3859
EOR
F002 40
F010 5.4
F004 7
F005 ME
F006 Groups of 10 male and 10 female rats were exposed to aerosol
**   concentrations of the three test materials at nominal
**   concentrations of 0, 50, 220 and 1000 mg/m3.
**   Exposures were for 6 hours each day, 5 days each week for 4
**   weeks. Total number
F007 Groups of 10 male and 10 female rats were exposed to aerosol
**   concentrations of the three test materials at nominal
**   concentrations of 0, 50, 220 and 1000 mg/m3.
**   Exposures were for 6 hours each day, 5 days each week for 4
**   weeks. Total number of exposures for each of the three test
**   materials was: 17, 18 and 20 days for SRO, WTO and HBO
**   respectively. Food and water were available ad libitum
**   during non-exposure periods.
**   Clinical observations were made prior to each exposure and
**   body weights were recorded weekly.
**   Animals were sacrificed within 72 hours of the last
**   exposure after being fasted overnight. Blood samples wee
**   taken for a range of hematology and serum chemical
**   parameters. The hematological parameters consisted of: Total
**   white and red  cells, hemoglobin, hematocrit, MCV, MCH, and
**   MCHC. A differential white cell count was also conducted.
**   The following chemical parameters were measured: Alanine
**   transferase, albumin, albumin/globulin ratio, alkaline
**   phosphatase, aspartate aminotransferase, total bilirubin,
**   calcium, chloride, cholesterol, creatinine, globulin,
**   glucose, iron, lactate dehydrogenase, inorganic phosphorus,
**   potassium, total protein, sodium, triglycerides, urea
**   nitrogen and uric acid.
**   All animals were necropsied and the following organs were
**   weighed: gonads, heart, kidneys, liver, spleen, and thymus.
**   The right middle lobe of the lung was weighed immediately
**   after removal and again after drying.
**   A range of tissues were fixed and prepared for a
**   histopathological examination.
**   Sperm from the cauda epididymis of each control and high
**   dose male was examined for an assessment of sperm
**   morphology.
F008 IUC31
F020 3860
EOR
F002 40
F010 5.4
F004 7
F005 RE
F006 Dalbey, W., Osimitz, T., Kommineni, C., Roy, T., Feuston,
**   M., and Yang, J. (1991)
```

** Four-week inhalation exposures of rats to aerosols of three
** lubricant bas oils
** J. Appl. Toxicol. Vol 11 (4), pp 297-302.
F007 Dalbey, W., Osimitz, T., Kommineni, C., Roy, T., Feuston,
** M., and Yang, J. (1991)
** Four-week inhalation exposures of rats to aerosols of three
** lubricant bas oils
** J. Appl. Toxicol. Vol 11 (4), pp 297-302.
F008 IUC4
F009 11-09-2010
F020 3861
EOR
F002 40
F010 5.4
F004 7
F005 RL
F006 It is not clear whether the study was carried out according
** to GLP, but otherwise it was a well conducted and well
** reported study.
F007 It is not clear whether the study was carried out according
** to GLP, but otherwise it was a well conducted and well
** reported study.
F008 IUC31
F020 3862
EOR
F002 40
F010 5.4
F004 7
F005 RS
F006 Chamber concentrations
** The aerosol concentrations were comparable among the three
** base stocks.
** Qualitatively, the aerosols were virtually identical to each
** liquid base oil.
** The actual concentrations for each of the aerosols was as
** follows:
F007 Chamber concentrations
** The aerosol concentrations were comparable among the three
** base stocks.
** Qualitatively, the aerosols were virtually identical to each
** liquid base oil.
** The actual concentrations for each of the aerosols was as
** follows:

	Nominal	Actual
SRO	0	0
	50	50 ±10
	220	210 ±10
	1000	1020 ±60
WTO	0	0
	50	50 ±10
	220	210 ±10
	1000	980 ±20
HBO	0	0
	50	47 ±2
	220	220 ±10

** 1000 980 ±50
**
** The mass median diameter was well under 2µm for each base
** stock
**
** Toxicity assessment
**
** Apart from occasional loose stool there were no treatment
** related clinical observations and body weights were
** unaffected by exposure.
** No treatment related effects were found in any of the
** hematological or clinical chemical parameters that were
** measured.
** The percent sperm with aberrant morphology, including
** breakage, was unaffected by exposure to any of the three
** base oils.
** There were no treatment-related observations at necropsy
** and, with the exception of the lungs, there were no
** significant changes in organ weights .
** Wet and dry lung weights increased in a dose-related manner.
** The percentage increases in wet weight are shown in the
** following table.
** For simplicity increases are shown to nearest whole
** numbers
** % Increase in wet lung weight
** Sex Dose SRO WTO HBO
** Female (mg/m3)
** 50 3 8 2
** 210 4 23* 34*
** 1000 38* 64* 36*
**
** Male
** 50 5 - 1
** 210 12* 1 6
** 1000 33* 31* 32*
** * denotes differences that are statistically significant
** (P<0.05) compared to controls.
** The ratios of wet to dry lung weights were significantly
** increased for both sexes at the highest dose concentration
** for all three base oils.
**
** Morphologically, treatment related changes were only
** observed in the lungs and tracheobronchial lymph nodes.
** Foamy macrophages with numerous vacuoles of varying size
** were present in the alveolar spaces of the lungs of many of
** the exposed animals. The histological changes are
** summarized in the following table.
**
** No. of animals in each group with a given
** histopathological change
**
** Tissue/change
** Dose group
** SRO 50 210 1000
** Lung
** 1-2 Foamy macrophages (FM) 20 20 20
** 3-6 FM 0 0 20

```
**   Thickened alveolar wall              0     0     0
**   FM in alveolar interstitium          0     0     0
**   Mild alveolar PMN infiltrate         0     5     20
**   Lymph nodes
**   Anterior mediastinal
**   Macrophage accumulation              NE    NE    9
**   Tracheobronchial
**   FM accumulation                      NE    NE    19
**   Macrophage accumulation              NE    NE    0
**
**   WTO
**   Lung
**   1-2 Foamy macrophages (FM)           20    20    20
**   3-6 FM                         0     0     20
**   Thickened alveolar wall              0     0     0
**   FM in alveolar interstitium          0     0     0
**   Mild alveolar PMN infiltrate         0     0     19
**   Lymph nodes
**   Anterior mediastinal
**   Macrophage accumulation              NE    NE    0
**   Tracheobronchial
**   FM accumulation                      NE    NE    0
**   Macrophage accumulation              NE    NE    19
**
**   HBO
**   Lung
**   1-2 Foamy macrophages (FM)           0     16    16
**   3-6 FM                         0     0     16
**   Thickened alveolar wall              0     0     16
**   FM in alveolar interstitium          0     0     16
**   Mild alveolar PMN infiltrate         0     0     0
**   Lymph nodes
**   Anterior mediastinal
**   Macrophage accumulation              NE    NE    2
**   Tracheobronchial
**   FM accumulation                      NE    NE    0
**   Macrophage accumulation              NE    NE    3
**
**          NE denotes Not Evaluated
**    Only 16 animals in the HBO high dose group were       examined
F008 IUC31
F020 3863
EOR
F002 40
F010 5.4
F004 7
F005 TS
F006 Three materials were examined in this study. The properties
**   of the materials designated SRO, WTO and HBO are shown in
**   the following table.
**
**   SRO    Solvent refined oil CAS # 64742-70-7
**
**   WTO    White oil CAS # 8042-47-5. [Prepared by severely
**    hydr
F007 Three materials were examined in this study. The properties
**   of the materials designated SRO, WTO and HBO are shown in
```

```
**   the following table.
**
**   SRO    Solvent refined oil CAS # 64742-70-7
**
**   WTO    White oil CAS # 8042-47-5. [Prepared by severely
**    hydrotreating a dewaxed feedstock and then acid       washing
**   with fuming sulfuric acid.]
**
**   HBO    Hydrotreated base oil CAS #64742-54-7  [Severely
**    hydrotreated heavy paraffinic oil produced by         treatment
**   of the vacuum distillate with hydrogen at  high temperature
**   and pressure (hydrotreating and      hydrocracking)].
**
**                      SRO   WTO   HBO
**
**   Viscosity at 100 °F            106   85    161
**   Pour point (°F)                20    15    -5
**   API Gravity              32.8  34.6  33.6
**   Furfural (ppm)                 1     0     <1
**   Nitrogen (ppm)                 44    -     8
**   Sulfur (wt.%)                  0.20  -     <0.06
**   Composition (wt.%)
**    Paraffins          36    60    29.7
**    Mononaphthenes           22.3  -     30.6
**    Polynaphthenes           22.3  -     37.3
**    Monoaromatics            12.8  0     0.6
**    Diaromatics        3.3   0     0.8
**    Polyaromatics            1.4   0     1.0
**    Unidentified aromatics   0.4   0     0
**    Aromatic sulfur types    1.1   0     0
F008 IUC31
F020 3864
EOR
F002 40
F010 5.4
F004 8
F005 ME
F006 Groups of 5 male and 5 female rats were exposed to oil mists
**   generated from two highly refined oils. Exposures were by
**   inhalation six hours each day for a total of 10 days
**   The two oils were examined in separate experiments.
**   The dose groups
F007 Groups of 5 male and 5 female rats were exposed to oil mists
**   generated from two highly refined oils. Exposures were by
**   inhalation six hours each day for a total of 10 days
**   The two oils were examined in separate experiments.
**   The dose groups were:
**
**   Group        Mean actual       Mass median
**          concentration          particle size
**          (mg/m3)                (µm)
**   Controls     Air only          N/A
**   Oil 1        55                1.5
**          507              1.9
**          1507             2.2
**
**   Oil 2        Air only          N/A
```

```
**          50                1.5
**          513               1.9
**          1480              2.2
**
**   No further experimental details are provided.
F008 IUC31
F020 3865
EOR
F002 40
F010 5.4
F004 8
F005 RE
F006 Skyberg, K., Skaug, V., Gylseth, B., Pedersen, J. R. and
**   Iversen, O. H. (1990)
**   Subacute inhalation toxicity of mineral oils, C15-C20
**   alkylbenzenes, and polybutene in male rats.
**   Environmental Research Vol. 53., pp 48-61
F007 Skyberg, K., Skaug, V., Gylseth, B., Pedersen, J. R. and
**   Iversen, O. H. (1990)
**   Subacute inhalation toxicity of mineral oils, C15-C20
**   alkylbenzenes, and polybutene in male rats.
**   Environmental Research Vol. 53., pp 48-61
F008 IUC31
F020 3866
EOR
F002 40
F010 5.4
F004 8
F005 RE
F006 Whitman, F. T., Freeman, J. J., Infurna, R. N. and Phillips,
**   R. D.  (1989)
**   Evaluation of the acute and subacute inhalation toxicity of
**   lubricating oil mists
**   The toxicologist Vol. 9., p 143
F007 Whitman, F. T., Freeman, J. J., Infurna, R. N. and Phillips,
**   R. D.  (1989)
**   Evaluation of the acute and subacute inhalation toxicity of
**   lubricating oil mists
**   The toxicologist Vol. 9., p 143
F008 IUC31
F020 3867
EOR
F002 40
F010 5.4
F004 8
F005 RL
F006 The information is taken from a poster presentation and a
**   reliability score cannot be assigned.
**   However, the data are supportive of the other study on
**   inhalation of oil mist reported by Dalbey et al.
F007 The information is taken from a poster presentation and a
**   reliability score cannot be assigned.
**   However, the data are supportive of the other study on
**   inhalation of oil mist reported by Dalbey et al.
F008 IUC31
F020 3868
EOR
```

F002 40
F010 5.4
F004 8
F005 RM
F006 A further two week inhalation study in rats has been
** reported for two mineral oil mists (Skyberg et al, 1990)
** The results largely confirm those described by Whitman et
** al. with respect to liver weight changes and histological
** observations i
F007 A further two week inhalation study in rats has been
** reported for two mineral oil mists (Skyberg et al, 1990)
** The results largely confirm those described by Whitman et
** al. with respect to liver weight changes and histological
** observations in respiratory tissues.
F008 IUC31
F020 3869
EOR
F002 40
F010 5.4
F004 8
F005 RS
F006 Oil 1
** All treated animals survived to study termination.
** The fur of all animals was saturated with test material and
** the amount of material present was clearly related to the
** exposure concentration.
** Alopecia and scabs subsequently formed in
F007 Oil 1
** All treated animals survived to study termination.
** The fur of all animals was saturated with test material and
** the amount of material present was clearly related to the
** exposure concentration.
** Alopecia and scabs subsequently formed in the highest 2 dose
** groups.
** Animals in the highest dose group were relatively
** unresponsive to auditory stimulation.
** Decreased body weight associated with a decrease in food
** consumption was recorded for the high dose animals.
**
** Biologically significant increases in relative lung and
** liver weights were observed in he males and females in the
** high dose group but only in the mid dose females.
** An increase in white cell counts and the percentage of
** neutrophils and a decrease in the percentage lymphocytes was
** observed in the high dose groups only.
** There were no treatment related histopathological changes in
** the lowest 2 dose groups. Animals in the highest dose group
** exhibited the same changes as those observed in the
** nasoturbinates and lungs of animals exposed to oil 2 (See
** below)
**
** Oil 2
** Clinical observations were the same as for those animals
** exposed to Oil 1, except that there was no scabbing and no
** treatment related alterations in food consumption.
** There was a biologically significant increase in absolute
** and relative lung weights in males and females at the high

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**   dose and in females only at the mid dose.
**   Apart from elevated liver alanine and aspartate transaminase
**   levels in the high dose females there were no other
**   treatment related effects.
**   Histological effects considered to be treatment related
**   consisted of an increase in the amount of perivascular and
**   peribronchial lymphoid proliferations and an increase in
**   mixed inflammatory cell infiltrations in the terminal
**   bronchioles and alveolar ducts of the highest two dose
**   groups. Increases in the appearance of focal hyperplasia and
**   squamous cell metaplasia of the anterior nasal mucosa
**   associated with inflammatory cell infiltration was observed
**   in the two highest dose groups. These changes were
**   indicative of mild irritation of the nasal mucosa.
**
**   The NOELs for the two oils were >50 mg/m3
F008 IUC31
F020 3870
EOR
F002 40
F010 5.5
F004 1
F005 CL
F006 Base stocks with no or low concentrations of PACs have low
**   Mutagenicity indices. Also, those oils that were negative in
**   the modified Ames assay (MI < 1.0) were not carcinogenic in
**   mouse skin painting studies.
**
**   Those oils which were positive
F007 Base stocks with no or low concentrations of PACs have low
**   Mutagenicity indices. Also, those oils that were negative in
**   the modified Ames assay (MI < 1.0) were not carcinogenic in
**   mouse skin painting studies.
**
**   Those oils which were positive in the modified Ames assay
**   had significant levels of PACs and were carcinogenic.
F008 IUC31
F020 3871
EOR
F002 40
F010 5.5
F004 1
F005 ME
F006 The method differed from the standard pre- incubation Ames
**   assay in the following respects.
**
**    A DMSO extract of the test materials was tested in    the
**   assay.
**
**    The S9 fraction was obtained from Araclor-induced
**    hamsters.
**
**    An eightfold conc
F007 The method differed from the standard pre- incubation Ames
**   assay in the following respects.
**
**    A DMSO extract of the test materials was tested in    the
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**   assay.
**
**    The S9 fraction was obtained from Araclor-induced
**    hamsters.
**
**    An eightfold concentration of S-9 was used in the     assays.
**
**    Twofold concentration of cofactor NADP was used.
**
**   The DMSO extracts were tested over a range of concentrations
**   that permitted the construction of a dose-response curve.
**
**   A Mutagenicity Index was determined for each assay. This was
**   the tangent to the dose response curve at zero dose.
**
**   An assay was judged to be positive if the Mutagenicity Index
**   was greater than 1.0
F008 IUC31
F020 3872
EOR
F002 40
F010 5.5
F004 1
F005 RE
F006 Blackburn, G. R., Deitch, R. A., Schreiner,C. A. and
**   Mackerer, C. R. (1986)
**   Predicting tumorigenicity of petroleum distillation
**   fractions using a modified Salmonella Mutagenicity assay.
**   Cell Biol. Toxicol. Vol. 2. pp 63-84
F007 Blackburn, G. R., Deitch, R. A., Schreiner,C. A. and
**   Mackerer, C. R. (1986)
**   Predicting tumorigenicity of petroleum distillation
**   fractions using a modified Salmonella Mutagenicity assay.
**   Cell Biol. Toxicol. Vol. 2. pp 63-84
F008 IUC31
F020 3873
EOR
F002 40
F010 5.5
F004 1
F005 RE
F006 Blackburn, G.R., Deitch, R.A., Schreiner, C.A., Mehlman, M.
**   A. and Mackerer, C.R. (1984)
**   Estimation of the dermal carcinogenic activity of petroleum
**   fractions using a modified Ames assay.
**   Cell Biol. and Toxicol. Vol 1, No 1, pp 67-80
F007 Blackburn, G.R., Deitch, R.A., Schreiner, C.A., Mehlman, M.
**   A. and Mackerer, C.R. (1984)
**   Estimation of the dermal carcinogenic activity of petroleum
**   fractions using a modified Ames assay.
**   Cell Biol. and Toxicol. Vol 1, No 1, pp 67-80
F008 IUC31
F020 3874
EOR
F002 40
F010 5.5
F004 1
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F005 RE
F006 Roy, T.A., Johnson, S.W., Blackburn, G.R., and Mackerer,
** C.R. (1988)
** Correlation of mutagenic and dermal carcinogenic activities
** of mineral oils with polycyclic aromatic compound content.
** Fund. Appl. Toxicol. Vol 10, pp 466-476
F007 Roy, T.A., Johnson, S.W., Blackburn, G.R., and Mackerer,
** C.R. (1988)
** Correlation of mutagenic and dermal carcinogenic activities
** of mineral oils with polycyclic aromatic compound content.
** Fund. Appl. Toxicol. Vol 10, pp 466-476
F008 IUC31
F009 23-09-2001
F020 3875
EOR
F002 40
F010 5.5
F004 1
F005 RS
F006 Roy describes the mutagenicity results for a range of
** petroleum-derived materials, 28 of which were lubricating
** oil base stocks.
** A Mutagenicity Index (MI) was determined for each test
** material and this was compared to the PAC content and to
F007 Roy describes the mutagenicity results for a range of
** petroleum-derived materials, 28 of which were lubricating
** oil base stocks.
** A Mutagenicity Index (MI) was determined for each test
** material and this was compared to the PAC content and to a
** carcinogenicity index that had also been determined for each
** material.
** The results were as follows.
**

** Sample		MI*	%PAC**	%T***	%T/LP****
** 5	0.9	0.9	0	4.17	
** 6	0	0.3	0	0	
** 7	0.9	0.9	2	4.17	
** 8	0	0.6	0	0	
** 9	0	0.3	0	0	
** 10	0	0.7	2	3.28	
** 12	2.4	3.1	4	5.93	
** 13	9.1	10	26	71	
** 14	0	0.7	2	3.45	
** 15	0	0.2	0	0	
** 16	3.9	3.7	6	1.6	
** 17	4	3.1	8	14.3	
** 18	3.6	4.9	10	21.7	
** 19	6.5	5.2	10	23.4	
** 20	9.2	7.7	40	138	
** 26	0	0.5	2	2	
** 27	0	0.5	2	3.92	
** 28	0	0.3	0	0	
** 29	0	0.6	0	0	
** 30	0	0.6	0	0	
** 32	10	12	54	154	
** 33	5.9	7.8	42	73.7	

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**    34    4.1   4.1   50    104
**    35    1.2   1.2   4     6.25
**    36    2.1   1.5   18    38.3
**    37    0     0.7   2     2.13
**    38    4.5   4.6   24    46.2
**    39    0     1.2   0     0
**
**    *     MI denotes Mutagenicity index.
**
**    **    %PAC is weight% of 3-7 ring PNAs in the oil.
**
**    ***   %T is the percentage of mice with tumors in          skin
**   carcinogenicity studies reported                elsewhere.
**
**    ****  %T/LP is the percentage of mice with tumors
**          multiplied by the reciprocal of the latency          period. The
**   author describes this as a                carcinogenic potency index.
F008 IUC31
F020 3876
EOR
F002 40
F010 5.5
F004 1
F005 TS
F006 The baseoils tested had PAC contents ranging from 0.2 to 12%.  It is
*    generally recognized that those base oils with PAC contents less than 3%
*    are highly refined oils whereas those with greater values are considered
*    to be poorly refined. Thi
F007 The baseoils tested had PAC contents ranging from 0.2 to 12%.  It is
*    generally recognized that those base oils with PAC contents less than 3%
*    are highly refined oils whereas those with greater values are considered
*    to be poorly refined. This distinction was recognized and used by the EU
*    in its classification of base oils. (Ref 70, 75)
F020 3877
EOR
F002 40
F010 5.5
F004 2
F005 ME
F006 The test substance (Canthus 1000, a deasphalted, dewaxed
**   residual oil) was diluted 1:5 in DMSO and then shaken,
**   centrifuged and separated into 2 fractions. Two assays were
**   conducted for the test substance: an initial assay and a
**   repeat assa
F007 The test substance (Canthus 1000, a deasphalted, dewaxed
**   residual oil) was diluted 1:5 in DMSO and then shaken,
**   centrifuged and separated into 2 fractions. Two assays were
**   conducted for the test substance: an initial assay and a
**   repeat assay. All plates were evaluated following
**   approximately two days of incubation. Test volumes of 5, 10,
**   15, 20, 30, 40, 50 and 60 µl/plate were prepared by dilution
**   of the DMSO fraction in DMSO and dosed at a final volume of
**   60 µl. The volumes were added to each plate with metabolic
**   activation (hamster S9) and tester strain TA98 following the
**   procedures outlined by Blackburn et al., (1986) and the
**   methods described in the American Society for Testing
**   Materials (ASTM) document, "The Standard Test Method for
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**   Determining Carcinogenic Potential of Virgin Base Oils in
**   Metalworking Fluids". The same test volumes were used in the
**   repeat assay.
**   A positive control and vehicle control were tested
**   concurrently.
**
**   Linear regression analysis (ASTM: E 1687-95) was performed
**   on the test substances which caused an increase in the mean
**   number of revertant colonies when compared to the vehicle
**   control. Only data from the linear portion of the dose
**   response curve was used to generate the mutagenicity index
**   (MI). If the increase in revertant colonies was not
**   statistically significant or if there was no increase in the
**   mean umber of revertant colonies, then the MI value was
**   considered to be 0 (revertants/µl DMSO extract).
**
**   Data from both the initial and repeat assays on the test
**   material (Canthus 1000) were pooled to generate a single
**   linear MI value. With this procedure, an MI value > 1.0
**   (revertants/µl DMSO extract) is considered indicative of a
**   potential dermal carcinogen in mice (Blackburn et al, 1996).
**   Conversely, a test substance is considered unlikely to be
**   carcinogenic in mouse skin when the MI value is < 1.0
**   (revertants/µl DMSO extract).
F008 IUC31
F020 3878
EOR
F002 40
F010 5.5
F004 2
F005 RE
F006 American Society of Testing Materials (ASTM)
**   The standard test method for determining carcinogenic
**   potential of virgin base oils in metalworking fluids
**   E-1687-98, Conshohocken, PA
F007 American Society of Testing Materials (ASTM)
**   The standard test method for determining carcinogenic
**   potential of virgin base oils in metalworking fluids
**   E-1687-98, Conshohocken, PA
F008 IUC4
F009 11-09-2010
F020 3879
EOR
F002 40
F010 5.5
F004 2
F005 RE
F006 Blackburn, G. R., Deitch, R. A., Schreiner,C. A. and
**   Mackerer, C. R. (1986)
**   Predicting tumorigenicity of petroleum distillation
**   fractions using a modified Salmonella Mutagenicity assay.
**   Cell Biol. Toxicol. Vol. 2. pp 63-84
F007 Blackburn, G. R., Deitch, R. A., Schreiner,C. A. and
**   Mackerer, C. R. (1986)
**   Predicting tumorigenicity of petroleum distillation
**   fractions using a modified Salmonella Mutagenicity assay.
**   Cell Biol. Toxicol. Vol. 2. pp 63-84
```

F008 IUC31
F020 3880
EOR
F002 40
F010 5.5
F004 2
F005 RE
F006 Blackburn, G. R., Roy, T. A., Bleicher Jr., W. T., Reddy, M.
** V. and Mackerer, C. R. (1996)
** Comparisons of biological and chemical predictors of dermal
** carcinogenicity of petroleum oils
** J. Polycyclic aromatic compounds Vol 11 pp 201-210
F007 Blackburn, G. R., Roy, T. A., Bleicher Jr., W. T., Reddy, M.
** V. and Mackerer, C. R. (1996)
** Comparisons of biological and chemical predictors of dermal
** carcinogenicity of petroleum oils
** J. Polycyclic aromatic compounds Vol 11 pp 201-210
F008 IUC4
F009 11-09-2010
F020 3881
EOR
F002 40
F010 5.5
F004 2
F005 RE
F006 Exxonmobil Biomedical Sciences Inc.
** (00MRL 18)
F007 Exxonmobil Biomedical Sciences Inc.
** (00MRL 18)
F008 IUC31
F020 3882
EOR
F002 40
F010 5.5
F004 2
F005 RL
F006 This summary is based on a summary of the results of a
** study.
** It is not possible, therefore to assign a reliabilty to this
** study.
** The data however are useful, together with other similar
** data to demonstrate that residual base oils are not
** m
F007 This summary is based on a summary of the results of a
** study.
** It is not possible, therefore to assign a reliabilty to this
** study.
** The data however are useful, together with other similar
** data to demonstrate that residual base oils are not
** mutagenic in a modified Ames assay.
F008 IUC31
F020 3883
EOR
F002 40
F010 5.5
F004 2
F005 RS

F006 The MI for Canthus 1000 was determined to be 0.2
** revertants/µl DMSO extract.
** Thus, under the conditions of this study, Canthus 1000 was
** considered negative for inducing frameshift mutations in
** Salmonella typhimurium.
F007 The MI for Canthus 1000 was determined to be 0.2
** revertants/µl DMSO extract.
** Thus, under the conditions of this study, Canthus 1000 was
** considered negative for inducing frameshift mutations in
** Salmonella typhimurium.
F008 IUC31
F020 3884
EOR
F002 40
F010 5.5
F004 3
F005 RE
F006 EMBSI
** 01.MRL.66
F007 EMBSI
** 01.MRL.66
F008 IUC31
F020 3885
EOR
F002 40
F010 5.5
F004 3
F005 RE
F006 Petrolabs (1998)
** H-Mobil-67763-Vacuum Resid.
F007 Petrolabs (1998)
** H-Mobil-67763-Vacuum Resid.
F008 IUC31
F020 3886
EOR
F002 40
F010 5.5
F004 3
F005 RE
F006 Petrolabs (2000)
** H-Mobil-68351-Bright stock
F007 Petrolabs (2000)
** H-Mobil-68351-Bright stock
F008 IUC31
F020 3887
EOR
F002 40
F010 5.5
F004 3
F005 RL
F006 This summary is based on a summary of the results of a
** study. It is not possible, therefore, to assign a
** reliability to this study.
** The data, however, are useful, together with other similar
** data, to demonstrate that residual base oils are
F007 This summary is based on a summary of the results of a
** study. It is not possible, therefore, to assign a

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**   reliability to this study.
**   The data, however, are useful, together with other similar
**   data, to demonstrate that residual base oils are not
**   mutagenic in a modified Ames assay.
F008 IUC31
F020 3888
EOR
F002 40
F010 5.5
F004 3
F005 RM
F006 Summaries are available on Modified Ames assays that have
**   been carried out on 3 additional residual base oils and a
**   vacuum residuum.
**   The results and references to the studies are shown below.
**   Under the conditions of this study, the test mat
F007 Summaries are available on Modified Ames assays that have
**   been carried out on 3 additional residual base oils and a
**   vacuum residuum.
**   The results and references to the studies are shown below.
**   Under the conditions of this study, the test materials were
**   considered negative for inducing frameshift mutations in
**   Salmonella typhimurium.
**
**   Material           Mutagenicity      Reference
**                Index (MI)
**
**   Vacuum residuum          0.8         Petrolabs (1998)
**   Bright stock       0.11        Petrolabs (2000)
**   150 SUS Bright stock     0           EMBSI
**   150 Solvent
**   Bright stock       0           EMBSI
F008 IUC31
F020 3889
EOR
F002 40
F010 5.6
F004 1
F005 ME
F006 A full description of the method is not given in the
**   publication.
**   The publication includes the following information:
**
**   The rat bone marrow cytogenetics assay was performed after
**   administration of each sample of the test materials to 5-10
**   ma
F007 A full description of the method is not given in the
**   publication.
**   The publication includes the following information:
**
**   The rat bone marrow cytogenetics assay was performed after
**   administration of each sample of the test materials to 5-10
**   males and 5-10 female Sprague Dawley rats per dose level.
**   In gavage studies, the samples were dissolved in corn oil or
**   saline and administered at a dosage of 5 ml/kg. Acute
**   studies and 5-day subchronic tests were performed in the
**   early stages of the work, but in subsequent assays only the
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** subchronic test was performed.
** A positive control chemical, triethylenemelamine (TEM) was
** tested concurrently.
F008 IUC31
F020 3890
EOR
F002 40
F010 5.6
F004 1
F005 RE
F006 Conaway,C. C., Schreiner, C. A. and Cragg, S. T. (1984)
** Mutagenicity evaluation of petroleum hydrocarbons
** In: Advances in modern experimental toxicology Volume VI:
** Applied toxicology of hydrocarbons, pp 89-107.
** Eds MacFarland et al., Prince
F007 Conaway,C. C., Schreiner, C. A. and Cragg, S. T. (1984)
** Mutagenicity evaluation of petroleum hydrocarbons
** In: Advances in modern experimental toxicology Volume VI:
** Applied toxicology of hydrocarbons, pp 89-107.
** Eds MacFarland et al., Princeton Scientific Publishers
F008 IUC31
F020 3891
EOR
F002 40
F010 5.6
F004 1
F005 RL
F006 The publication presents a summary of a program of work
** carried out for the API.
** Since raw data are not presented in the publication, a
** reliability rating cannot be assigned.
** Nevertheless, the information is useful in demonstrating the
** lack
F007 The publication presents a summary of a program of work
** carried out for the API.
** Since raw data are not presented in the publication, a
** reliability rating cannot be assigned.
** Nevertheless, the information is useful in demonstrating the
** lack of in-vivo genotoxic activity of the base oils
** containing low levels of PACs.
F008 IUC31
F020 3892
EOR
F002 40
F010 5.6
F004 1
F005 RS
F006 The results tabulated in the publication are as follows:
**
** Sample Dose No. animals No. cells Aberrant
** (mg/kg) cells (%)
**
** Paraffinic oils
** 64 SUS Corn oil 8 400 4.3
** 500 10 500 3.8
** 1000 9 450 2
** 2000 10 500 2.8

```
**   133 SUS
**    Corn oil    1
F007 The results tabulated in the publication are as follows:
**
**   Sample Dose  No. animals No. cells   Aberrant
**    (mg/kg)                            cells (%)
**
**   Paraffinic oils
**   64 SUS Corn oil    8     400         4.3
**    500          10    500         3.8
**    1000         9     450         2
**    2000         10    500         2.8
**   133 SUS
**    Corn oil     10    500         3
**    500          8     400         1.3
**    1000         10    500         2
**    2000         10    500         1
**   331 SUS
**    Corn oil     10    500         4
**    500          9     450         3.8
**    1000         8     450         5.6
**    2000         10    500         7*
**   485 SUS
**    Corn oil     7     350         4
**    500          9     450         4.9
**    1000         8     400         4.3
**    2000         7     350         5.7
**   990 SUS
**    Corn oil     8     400         1
**    500          6     300         1.3
**    1000         9     450         1.6
**    2000         8     400         2.5
**
**   Naphthenic oils
**   80 SUS Saline            19    950         0.4
**    500          17    850         0.4
**    1670         19    950         0.6
**    5000         20    1000        0.4
**   2000 SUS
**    Saline             19    950         0.7
**    500          18    874         0.7
**    1670         18    900         1.6
**    5000         15    750         0.4
**   TEM
**    0.4-1.0                          24.2-41.8*
**
**   * denotes significant by Wilcoxon rank test
F008 IUC31
F020 3893
EOR
F002 40
F010 5.6
F004 1
F005 TS
F006 Two naphthenic and 5 paraffinic base stocks were tested. The
**   characteristics of the samples tested are as follows:
**
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**   Sample       Initial           Aromatics   PNAs
**          boiling           (%)         (%)
**          point
**          (° F)
**   Paraffinic oils
**   SUS at 100 °F
**   64           536         10.2        0.4
**   133          63
F007 Two naphthenic and 5 paraffinic base stocks were tested. The
**   characteristics of the samples tested are as follows:
**
**   Sample       Initial           Aromatics   PNAs
**          boiling           (%)         (%)
**          point
**          (° F)
**   Paraffinic oils
**   SUS at 100 °F
**   64           536         10.2        0.4
**   133          639         13.8        0.7
**   331          636         28.1        3.0
**   485          572         27.8        4.1
**   990          515         31.9        4.8
**   Naphthenic oils
**   SUS at 100 °F
**   80           470         23.8        0.8
**   2000         611         37.7        4.5
F008 IUC31
F020 3894
EOR
F002 40
F010 5.7
F004 2
F005 RE
F006 Bingham, E. Trosset, R. P., Warshawsky, D. (1980)
**   Carcinogenic potential of petroleum hydrocarbons, a critical
**   review of the literature.
**   J. Environmental Pathology and Toxicology, Vol 3, pp
**   483-563.
F007 Bingham, E. Trosset, R. P., Warshawsky, D. (1980)
**   Carcinogenic potential of petroleum hydrocarbons, a critical
**   review of the literature.
**   J. Environmental Pathology and Toxicology, Vol 3, pp
**   483-563.
F008 IUC31
F020 3895
EOR
F002 40
F010 5.7
F004 2
F005 RE
F006 Blackburn, G.R., Deitch, R.A., Schreiner, C.A., Mehlman, M.
**   A. and Mackerer, C.R. (1984)
**   Estimation of the dermal carcinogenic activity of petroleum
**   fractions using a modified Ames assay.
**   Cell Biol. and Toxicol. Vol 1, No 1, pp 67-80
F007 Blackburn, G.R., Deitch, R.A., Schreiner, C.A., Mehlman, M.
**   A. and Mackerer, C.R. (1984)
```

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**   Estimation of the dermal carcinogenic activity of petroleum
**   fractions using a modified Ames assay.
**   Cell Biol. and Toxicol. Vol 1, No 1, pp 67-80
F008 IUC31
F020 3896
EOR
F002 40
F010 5.7
F004 2
F005 RE
F006 CONCAWE (1994)
**   The use of the dimethyl sulphoxide (DMSO) extract by the IP
**   346 method as an indicator of the carcinogenicity of
**   lubricant base oils and distillate aromatic extracts.
**   CONCAWE Report No. 94/51
**   CONCAWE, Brussels.
F007 CONCAWE (1994)
**   The use of the dimethyl sulphoxide (DMSO) extract by the IP
**   346 method as an indicator of the carcinogenicity of
**   lubricant base oils and distillate aromatic extracts.
**   CONCAWE Report No. 94/51
**   CONCAWE, Brussels.
F008 IUC31
F020 3897
EOR
F002 40
F010 5.7
F004 2
F005 RE
F006 CONCAWE (1997)
**   Lubricating oil basestocks
**   Product dossier No. 97/108
**   CONCAWE, Brussels
F007 CONCAWE (1997)
**   Lubricating oil basestocks
**   Product dossier No. 97/108
**   CONCAWE, Brussels
F008 IUC31
F020 3898
EOR
F002 40
F010 5.7
F004 2
F005 RE
F006 IARC (1984)
**   IARC Monographs on the evaluation of the carcinogenic risk
**   of chemicals to humans, Volume 33: Polynuclear aromatic
**   hydrocarbons, part 2, carbon blacks, mineral oils (lubricant
**   base oils and derived products) and some nitroarenes
F007 IARC (1984)
**   IARC Monographs on the evaluation of the carcinogenic risk
**   of chemicals to humans, Volume 33: Polynuclear aromatic
**   hydrocarbons, part 2, carbon blacks, mineral oils (lubricant
**   base oils and derived products) and some nitroarenes.
**   International Agency for Research on Cancer, Lyon.
F008 IUC31
F020 3899
```

EOR
F002 40
F010 5.7
F004 2
F005 RE
F006 Roy, T.A., Johnson, S.W., Blackburn, G.R., and Mackerer,
** C.R. (1988)
** Correlation of mutagenic and dermal carcinogenic activities
** of mineral oils with polycyclic aromatic compound content.
** Fund. Appl. Toxicol. Vol 10, pp 466-476
F007 Roy, T.A., Johnson, S.W., Blackburn, G.R., and Mackerer,
** C.R. (1988)
** Correlation of mutagenic and dermal carcinogenic activities
** of mineral oils with polycyclic aromatic compound content.
** Fund. Appl. Toxicol. Vol 10, pp 466-476
F008 IUC31
F009 23-09-2001
F020 3900
EOR
F002 40
F010 5.7
F004 2
F005 RM
F006 Numerous skin carcinogenicity studies have been carried out
** on lubricating base oils derived from distillates. Data from
** these studies have been summarized and reviewed elsewhere.
**
** No single study is summarized here but the general
** conclusi
F007 Numerous skin carcinogenicity studies have been carried out
** on lubricating base oils derived from distillates. Data from
** these studies have been summarized and reviewed elsewhere.
**
** No single study is summarized here but the general
** conclusions that may be drawn from the numerous studies are:
**
** Highly refined base oils are not skin carcinogens.
**
** Poorly refined or unrefined base oils are skin
** carcinogens.
**
** A good correlation exists between skin carcinogenic
** potential and level of DMSO extractables and polycyclic
** aromatic compounds present in the base oil.
**
** The degree of carcinogenicity is dependent on the level of
** polycyclic aromatic compounds present in the base oil.
**
** When applied repeatedly to the skin, carcinogenic base
** oils are associated only with skin tumors and not with an
** increase in systemic tumors.
**
** There is a good correlation between skin carcinogenicity
** and Mutagenicity Index as determined in a modified Ames
** assay.
F008 IUC31
F020 3901

EOR
F002 40
F010 5.7
F004 4
F005 RE
F006 ExxonMobil (2001)
** Combined chronic toxicity/carcinogenicity study of white oil
** in Fischer 344 rats. Test substance 70cSt White oil.
** Study performed for CONCAWE
** Project No. 105970
** Exxon Biomedical Sciences Inc. New Jersey July 11, 2001
F007 ExxonMobil (2001)
** Combined chronic toxicity/carcinogenicity study of white oil
** in Fischer 344 rats. Test substance 70cSt White oil.
** Study performed for CONCAWE
** Project No. 105970
** Exxon Biomedical Sciences Inc. New Jersey July 11, 2001
F008 IUC4
F009 11-09-2010
F020 3902
EOR
F002 40
F010 5.7
F004 4
F005 RM
F006 This study is a study that was conducted according to OECD
** guidelines. It is not described in full in this summary
** since it is not one of the SIDS base set requirements.
F007 This study is a study that was conducted according to OECD
** guidelines. It is not described in full in this summary
** since it is not one of the SIDS base set requirements.
F008 IUC31
F020 3903
EOR
F002 40
F010 5.7
F004 4
F005 RS
F006 Survival was unaffected by exposure to the test material.
** There were no treatment related clinical signs, or any
** effects on body weight, food consumption, food conversion
** efficiency or ophthalmology. Furthermore, there was no
** treatment rela
F007 Survival was unaffected by exposure to the test material.
** There were no treatment related clinical signs, or any
** effects on body weight, food consumption, food conversion
** efficiency or ophthalmology. Furthermore, there was no
** treatment related effects on the hematological, serum
** chemistry or urinalysis parameters that were measured.
** At gross necropsy, there were no treatment-related gross
** observations and there were no treatment-related neoplastic
** changes.
F008 IUC31
F020 3904
EOR
F002 40
F010 5.7

F004 4
F005 TS
F006 The test material is a 70 cSt white oil with an average
** molecular weight of 485.
F007 The test material is a 70 cSt white oil with an average
** molecular weight of 485.
F008 IUC31
F020 3905
EOR
F002 40
F010 5.7
F004 5
F005 RE
F006 Shoda, T, Toyoda, K, Uneyama, C., Takada, K. and Takahashi,
** M. (1997)
** Lack of carcinogenicity of medium-viscosityy liquid paraffin
** given in the diet to F344 rats.
** Food and Chemical Toxicology Vol. 35, pages 1181-1190
F007 Shoda, T, Toyoda, K, Uneyama, C., Takada, K. and Takahashi,
** M. (1997)
** Lack of carcinogenicity of medium-viscosityy liquid paraffin
** given in the diet to F344 rats.
** Food and Chemical Toxicology Vol. 35, pages 1181-1190
F008 IUC31
F020 3906
EOR
F002 40
F010 5.7
F004 5
F005 RL
F006 Although the experimental details are not provided here, the
** information is nevertheless useful in establishing the lack
** of carcinogenicity by the oral route.
F007 Although the experimental details are not provided here, the
** information is nevertheless useful in establishing the lack
** of carcinogenicity by the oral route.
F008 IUC31
F020 3907
EOR
F002 40
F010 5.7
F004 5
F005 RS
F006 There were slight increases in body weights in both sexes of
** the 5% group (5% for males and 2.7% for females) at week
** 104. Food consumption was also increased in the 5% groups
** (11% for males and 8% for females total increase at week
** 104). H
F007 There were slight increases in body weights in both sexes of
** the 5% group (5% for males and 2.7% for females) at week
** 104. Food consumption was also increased in the 5% groups
** (11% for males and 8% for females total increase at week
** 104). However, no significant treatment-related differences
** between the control and treated groups were observed for
** clinical signs, mortality or hematological findings.
** In the 5% group, absolute liver and kidney weights were
** increased in males and absolute and relative submaxillary

** gland weight were reduced in females. Absolute and relative
** weights of heart and spleen were unaffected by treatment.
** The percentage increases/decreases in the 5% group were:
**
** Organ Absolute Relative
**
**
** Female
** Submaxillary gland 3% decrease 1.7% decrease
**
** Male
** Liver 8.4% increase not different
** Kidney (R) 14.9% increase not different
** Kidney (L) 9.9% increase not different
**
** In the 5% male group, the increased absolute organ weights
** were attributed to the slight increases in body weights.
**
** A variety of tumors developed in all groups, including the
** control group. However, all the neoplastic lesions were
** histologically similar to those known to occur spontaneously
** in F344 rats, and no statistically significant increase in
** the incidence of any tumor type was found for either sex in
** the treated groups.
**
** Granulomatous inflammation in the mesenteric lymph nodes,
** considered to be a reaction to paraffin absorption, was
** observed with similar incidence and severity in both sexes
** of the 2.5 and 5% groups.
**
** The authors concluded that under the present experimental
** conditions, the high dose, about 2000-200,000 times higher
** than the current temporary acceptable daily intake, did not
** have any carcinogenic potential in F344 rats. Furthermore,
** the granulomatous inflammation observed in the mesenteric
** lymph nodes was not associated with any development of
** neoplastic lesions.
F008 IUC31
F020 3908
EOR
F002 40
F010 5.7
F004 5
F005 TS
F006 The test material was composed of equal quantities of eight
** different commercially available liquid paraffins (highly
** refined white oils) obtained from eight member companies of
** the Japan Liquid Paraffin Industry.
** Each of the eight liquid p
F007 The test material was composed of equal quantities of eight
** different commercially available liquid paraffins (highly
** refined white oils) obtained from eight member companies of
** the Japan Liquid Paraffin Industry.
** Each of the eight liquid paraffins complied with the
** requirements of the Japanese food additive and Japanese
** Pharmacopoeia standards. 5 of the component material had
** been derived from petroleum by acid treatment and the other

```
**   eight had been derived by hydrotreatment.
**   The physical properties of a sample of the composite test
**   material were determined by CONCAWE and were as follows:
**
**   Viscosity at 40°C                    0.871
**   Viscosity at 100 °C                        8.68
**   Ratio of naphthenic/paraffinic hydrocarbon 35/65
**   Average molecular weight             475
**   Carbon No. at 5% boiling point             25
F008 IUC31
F020 3909
EOR
F002 40
F010 5.7
F004 6
F005 ME
F006 0.01 ml of undiluted test material was spread three times
**   weekly over the shorn dorsal skin of a group of 50 female CF
**   No.1 mice. A further two groups of 5 female mice underwent
**   similar treatment and were killed after 22 or 52 weeks.
**
**   The
F007 0.01 ml of undiluted test material was spread three times
**   weekly over the shorn dorsal skin of a group of 50 female CF
**   No.1 mice. A further two groups of 5 female mice underwent
**   similar treatment and were killed after 22 or 52 weeks.
**
**   The appearance and development (or regression) of
**   superficial tissue masses was recorded weekly throughout the
**   study, to enable calculation of the latency period of those
**   subsequently diagnosed as being tumors.
**
**   A positive control group of 50 female mice was treated with
**   an oil (N1) that had been shown in previous studies to be a
**   skin carcinogen. The mice in the positive control group
**   received the oil once a week for 22 weeks and then once
**   every 14 days for a total of 78 weeks.
**   A group of 50 untreated female mice served as negative
**   controls.
F008 IUC31
F020 3910
EOR
F002 40
F010 5.7
F004 6
F005 RE
F006 King, D. J. (1991)
**   1156, 1157 and 1158: 2-Year skin painting study.
**   Toxicology report 25-90-0275
**   BP Group Occupational Health Centre
F007 King, D. J. (1991)
**   1156, 1157 and 1158: 2-Year skin painting study.
**   Toxicology report 25-90-0275
**   BP Group Occupational Health Centre
F008 IUC31
F020 3911
EOR
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F002 40
F010 5.7
F004 6
F005 RL
F006 This report is a summary report and as a consequence does
** not provide full experimental details, but does provide
** sufficient information for a conclusion to be made on the
** skin carcinogenic potential of a non-solvent refined
** residual paraff
F007 This report is a summary report and as a consequence does
** not provide full experimental details, but does provide
** sufficient information for a conclusion to be made on the
** skin carcinogenic potential of a non-solvent refined
** residual paraffinic base oil.
F008 IUC31
F020 3912
EOR
F002 40
F010 5.7
F004 6
F005 RS
F006 Minimal evidence of skin irritation was visible following
** treatment with the test materials.
** No treatment-related effects were observed on clinical
** condition, body weight gain or mortality (NB survival rates
** for treated animals are not incl
F007 Minimal evidence of skin irritation was visible following
** treatment with the test materials.
** No treatment-related effects were observed on clinical
** condition, body weight gain or mortality (NB survival rates
** for treated animals are not included in the report).
** Changes recorded at post mortem were considered normal.
** Histopathological examination of the skin of the treated
** mice provided no evidence of skin irritation and no tumors
** of epidermal origin were observed.
**
** No cutaneous tumors were recorded in the group of untreated
** control mice (52% of animals survived to termination after 2
** years)
**
** The positive control group had skin reactions at the
** treatment site which included redness, scabbing, cracking
** and flaking; histopathological examination confirmed the
** presence of chronic inflammation (acanthosis,
** hyperkeratosis, ulcers, parakeratosis and scabs). In
** addition, skin reactions, principally at the margins of the
** treatment site were frequently recorded and were
** particularly seen during the first 22 weeks of treatment.
** These reactions typically included abrasions and ulceration.
** The severity of the lesions was such that many animals were
** killed on humane grounds; only 24% of animals survived to 78
** weeks.
** Histopathological examination of the skin revealed that over
** 78 weeks, 23 mice in the positive control group had 56
** tumors of epidermal origin, of which 39 were benign
** (papillomas and keratoacanthomas) and 17 were malignant
** (squamous cell carcinomas and one single malignant basal

**   cell tumor). The mean latency period was 37 weeks.
F008 IUC31
F020 3913
EOR
F002 40
F010 5.7
F004 6
F005 TS
F006 The test substance was described as:
**   "A non-solvent refined, deasphalted, dewaxed residual
**   paraffinic lubricant base oil"
**
**   Characteristic   Value
**   Kinematic viscosity
**   at 40 deg C   1024 cSt
**   at 60 deg C   266.6 cSt
**   at 100 deg C   42.52
F007 The test substance was described as:
**   "A non-solvent refined, deasphalted, dewaxed residual
**   paraffinic lubricant base oil"
**
**   Characteristic   Value
**   Kinematic viscosity
**   at 40 deg C   1024 cSt
**   at 60 deg C   266.6 cSt
**   at 100 deg C   42.52 cSt
**   Density at 15 deg C   0.9280 kg/l
**   Pour point   +3 deg C
**   Flash point (COC)   315 deg C
**   Refractive index   1.5142
**   Color (D1500)   8.0
**   Molecular weight (D2502)   660
**   Sulfur   1.7% wt
**   Aniline point   105.0 deg C
**   Volatiles 3 hrs at 13 deg C   0.10%
**   Neutralization value   0.02 mg KOH/g
**   Viscosity gravity constant (D2140)   0.846
**   Refractivity intercept   1.0598
**   Molecular type (D2007)
**   Saturates   46.3% wt
**   Aromatics   45.6% wt
**   Polars   8.0% wt
**   Carbon type (D2140)
**   CA   15%
**   CN   19%
**   CP   66%
**
**   Total and individual PCA concentrations on completion of
**   study
**   Individual PCA   mg/kg
**   Fluoranthene   0.2
**   Pyrene   0.9
**   Benz(a)anthracene   0.3
**   Chrysene/triphenylene   2.5
**   Benzofluoroanthenes   1.0
**   Benzo(e)pyrene   1.6
**   Benzo(a)pyrene   0.1

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**   Perylene                          0.1
**   Dibenz(a,j)anthracene                   <0.1
**   Dibenz(a,h)anthracene                   <0.1
**   Indeno(1,2,3-cd)pyrene                  <0.1
**   Benzo(ghi)perylene                <0.1
**   Total PCA content (BP3 method)          7.0% wt
F008 IUC31
F020 3914
EOR
F002 40
F010 5.7
F004 7
F005 ME
F006 The summary states that the design of the study was similar
**   to other conventional skin painting studies in mice.
**
**   The test material was applied undiluted in 25 µl aliquots to
**   the clipped dorsal back regions of 50 male C3H/HeJ mice,
**   three ti
F007 The summary states that the design of the study was similar
**   to other conventional skin painting studies in mice.
**
**   The test material was applied undiluted in 25 µl aliquots to
**   the clipped dorsal back regions of 50 male C3H/HeJ mice,
**   three times weekly. At each treatment period, the dorsal
**   skin was examined for the presence of papillomas/carcinomas,
**   and each animal was also examined daily for any clinical
**   signs of ill health. Treatment continued for 24 months. A
**   complete necropsy was conducted at the time of sacrifice. In
**   this study, Primol 185, a medicinal grade white mineral oil
**   was applied undiluted and served as the negative control.
**   Heavy Clarified Oil (HCO) was applied as a 10% solution in
**   Primol 185, and served as the positive control.
F008 IUC31
F020 3915
EOR
F002 40
F010 5.7
F004 7
F005 RE
F006 Exxon
**   REHD (MR.32DO.84)
F007 Exxon
**   REHD (MR.32DO.84)
F008 IUC31
F020 3916
EOR
F002 40
F010 5.7
F004 7
F005 RL
F006 The information given is based on a summary of the study and
**   hence it is not possible to assign reliability to the study.
**   Nevertheless, the data provide useful information on the
**   carcinogenic potential of residual base oils.
F007 The information given is based on a summary of the study and
**   hence it is not possible to assign reliability to the study.
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**   Nevertheless, the data provide useful information on the
**   carcinogenic potential of residual base oils.
F008 IUC31
F020 3917
EOR
F002 40
F010 5.7
F004 7
F005 RS
F006 None of the animals treated with the test material or the
**   negative control material developed skin tumors, or any
**   other tumors considered treatment-related, over the course
**   of the study. The positive control material, 10% HCO,
**   responded as
F007 None of the animals treated with the test material or the
**   negative control material developed skin tumors, or any
**   other tumors considered treatment-related, over the course
**   of the study. The positive control material, 10% HCO,
**   responded as anticipated, producing squamous cell carcinomas
**   in 47 of 50 treated animals.
F008 IUC31
F020 3918
EOR
F002 40
F010 5.8.1
F004 1
F005 ME
F006 The method used was as described in OECD guideline 421.
**
**   The base oil was administered by gavage at a dose of 1.15
**   mg/kg (bw) to a group of 12 male and 12 female Sprague
**   Dawley
**   rats. Rats designated F0 animals were dosed for a
**   minimum of 14
F007 The method used was as described in OECD guideline 421.
**
**   The base oil was administered by gavage at a dose of 1.15
**   mg/kg (bw) to a group of 12 male and 12 female Sprague
**   Dawley
**   rats. Rats designated F0 animals were dosed for a
**   minimum of 14 days prior to mating. Dosing was continued
**   after mating until a total dosing period of 30 days had
**   elapsed for males and until day 4 of lactation for females
**   (39 days).
**   The animals were observed twice daily for appearance,
**   behavior, moirbundity and mortality. Males and females were
**   also observed during dosing and for one hour thereafter.
**   Male F0 body weights were recorded weekly. Female F0 body
**   weights were also recorded weekly until evidence of mating
**   was observed and then on gestation days 0, 7, 14 and 20 and
**   on lactation days 1 and 4. Food consumption was also
**   recorded for F0 both sexes.
**   Animals were paired on a 1:1 basis. Positive evidence of
**   mating was confirmed either by the presence of sperm in a
**   vaginal smear or a vaginal plug. The day when evidence of
**   mating was identified was termed Day 0 of gestation.
**
```

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**   The following Fertility indices were calculated:
**    Female mating index
**    Male mating index
**    Female fertility index
**    Male fertility index
**
**   All females were allowed to deliver their young naturally
**   and rear them to post-natal day 4. Females were observed
**   twice daily during the period of expected parturition for
**   initiation and completion of parturition and for signs of
**   dystocia. After parturition, litters were sexed and examined
**   for evidence of gross malformations, numbers of stillborn
**   and live pups.
**   Litters were examined daily and each pup received a detailed
**   physical examination on days 1 and 4 of lactation. Any
**   abnormalities were recorded.
**   The live litter size and viability index were calculated.
**   All surviving pups were necropsied on post-natal day 4.
**   A complete gross examination was made on all animals at
**   necropsy.
**   Selected organs of parental animals were weighed and a wide
**   range of tissues was fixed for subsequent histopathological
**   examination.
F008 IUC31
F020 3919
EOR
F002 40
F010 5.8.1
F004 1
F005 RE
F006 WIL Research Laboratories Inc. (1995)
**   An oral reproduction/developmental toxicity screening study
**   of **** in finished oil in rats.
**   Laboratory Study No. WIL-187007
F007 WIL Research Laboratories Inc. (1995)
**   An oral reproduction/developmental toxicity screening study
**   of **** in finished oil in rats.
**   Laboratory Study No. WIL-187007
F008 IUC31
F020 3920
EOR
F002 40
F010 5.8.1
F004 1
F005 RL
F006 The study was on an oil additive in base oil at two
**   concentrations. The base oil alone was used as the control.
**   Therefore, no control was available with which to compare
**   the
**   study control group. However, since all the recorded values
**   were w
F007 The study was on an oil additive in base oil at two
**   concentrations. The base oil alone was used as the control.
**   Therefore, no control was available with which to compare
**   the
**   study control group. However, since all the recorded values
**   were within normal limits, it could be concluded that the
```

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**   base oil was without effect.
F008 IUC31
F020 3921
EOR
F002 40
F010 5.8.1
F004 1
F005 RS
F006 Only the results for the base oil control group are reported
**   below.
**
**   There were no clinical findings and growth rates and food
**   consumption values were normal.
**   Fertility indices and mating indices for males and females
**   were both 100%.
**   At nec
F007 Only the results for the base oil control group are reported
**   below.
**
**   There were no clinical findings and growth rates and food
**   consumption values were normal.
**   Fertility indices and mating indices for males and females
**   were both 100%.
**   At necropsy, there were no consistent findings and the
**   animals were considered to be normal.
**   Organ weights and histopathology was considered normal.
F008 IUC31
F020 3922
EOR
F002 40
F010 5.8.1
F004 2
F005 ME
F006 72 female and 36 male Sprague-Dawley rats were given white
**   oil at a dose of 5 ml/kg, 5 days a week for 13 weeks.  After
**   this time each of the males was housed with 2 females for 10
**   consecutive nights, or until mating was confirmed by the
**   ap
F007 72 female and 36 male Sprague-Dawley rats were given white
**   oil at a dose of 5 ml/kg, 5 days a week for 13 weeks.  After
**   this time each of the males was housed with 2 females for 10
**   consecutive nights, or until mating was confirmed by the
**   appearance of a copulatory plug or by the presence of sperm
**   in a vaginal rinse.
**   The mated females were maintained without further dosing
**   through gestation and lactation to post-partum day 21.
**   Detailed maternal physical examinations and body weight
**   measurements were made on days 0, 7, 14 and 21 of gestation
**   and on days 0, 4, 14 and 21 of lactation.
**   All dams and surviving litters were sacrificed and grossly
**   examined on day 21 of lactation.  Each of the offspring was
**   examined for external malformations.  All pups were then
**   sacrificed, necropsied and subjected to visceral organ and
**   brain examination.  Pups which died spontaneously were also
**   necropsied unless this was precluded by cannibalism or
**   aut
F008 IUC31
```

F020 3923
EOR
F002 40
F010 5.8.1
F004 2
F005 RE
F006 McKee, R. H., Plutnick, R. T. and Traul, K. A. (1987)
** Assessment of the potential reproductive and subchronic
** toxicity of EDS coal liquids in Sprague-Dawley rats.
** Toxicology Vol 46, pp 267-280
F007 McKee, R. H., Plutnick, R. T. and Traul, K. A. (1987)
** Assessment of the potential reproductive and subchronic
** toxicity of EDS coal liquids in Sprague-Dawley rats.
** Toxicology Vol 46, pp 267-280
F008 IUC31
F020 3924
EOR
F002 40
F010 5.8.1
F004 2
F005 RL
F006 Not all the raw data are presented in this publication.
** However, the data are useful in determining that white oils
** do not cause effects on reproduction after prior exposure
** for 13 weeks.
F007 Not all the raw data are presented in this publication.
** However, the data are useful in determining that white oils
** do not cause effects on reproduction after prior exposure
** for 13 weeks.
F008 IUC31
F020 3925
EOR
F002 40
F010 5.8.1
F004 2
F005 RM
F006 White oil was used as solvent control in a study to
** determine the effects of two EDS coal liquids in a 13 week
** subchronic a single generation reproduction study.
** There were three dose groups and a control
** group for each test material in thi
F007 White oil was used as solvent control in a study to
** determine the effects of two EDS coal liquids in a 13 week
** subchronic a single generation reproduction study.
** There were three dose groups and a control
** group for each test material in this study.
** The information in this robust summary relates only to the
** white oil control groups (one for each of the test
** materials) and NOT to the groups exposed to EDS coal
** liquids.
**
** The CAS# for the material that was used in this study is not included in
* the Lubricating Base Stocks category. However, because white oils are so
* highly purified, toxicologically and compositionally they are all very
* similar. Therefore, the Testing Group thinks the results on CAS #
* 8012-95-1 are applicable to the highly refined base oils that are
* included in this category.

F008 IUC31
F020 3926
EOR
F002 40
F010 5.8.1
F004 2
F005 RS
F006 The data for the two control groups are summarized below.
**
** Parameter Control 1 Control 2
**
** Impregnation 80.8% 80.9
** frequency
**
** Gestation 22.6 days 22.6
** Pups delivered 11.7 11.1
** Live births 11.2 10.7
** Survival at day 4 10.5 9.6
** Surviva
F007 The data for the two control groups are summarized below.
**
** Parameter Control 1 Control 2
**
** Impregnation 80.8% 80.9
** frequency
**
** Gestation 22.6 days 22.6
** Pups delivered 11.7 11.1
** Live births 11.2 10.7
** Survival at day 4 10.5 9.6
** Survival at day 14 10.2 9.3
** Survival at day 21 10.1 9.3
**
** Offspring body weights
** Day 0 lactation 6.7 6.9
** Day 4 lactation 9.3 9.9
** Day 14 lactation 26.9 27.1
** Day 21 lactation 43.2 46.7
**
** No unusual behavior was reported during the gestation
** period for either of the control groups.
** The general condition of offspring and dams was good through
** weaning.
** Gross observations of pups and dams were generally
** unremarkable.
** In one base oil group, 3 malformed pups were found in 2
** litters. Two of the malformed pups had syndactyly and renal
** agenesis and one of these also exhibited agnathia. The third
** pup had a small eye.
**
** In the other control group, four malformed pups were found
** in 4 litters. Two of the pups had tail abnormalities, one
** had a
** depression in the sternum and the fourth had a short snout.
**
** The authors comment that a similar spectrum of malformations
** in Sprague-Dawley rats from the same supplier has been

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**   reported elsewhere. The authors also comment that this
**   spectrum of malformations can occur spontaneously in the
**   Sprague-Dawley rat and are not regarded as
**   treatment-related.
F008 IUC31
F020 3927
EOR
F002 40
F010 5.8.1
F004 2
F005 TS
F006 The test substance is not listed in the US HPV program.
**   Nevertheless, it is a white oil and the results are directly
**   applicable to other highly refined white oils.
F007 The test substance is not listed in the US HPV program.
**   Nevertheless, it is a white oil and the results are directly
**   applicable to other highly refined white oils.
F008 IUC31
F020 3928
EOR
F002 40
F010 5.8.2
F004 1
F005 ME
F006 Two groups of animals (50 and 25)were administered white oil
**   by gavage at a dose of 5 ml/kg, every day during gestation
**   days 6 to 19 inclusive.  Food and water were available
**   continuously.  Animals were examined for viability and
**   clinical e
F007 Two groups of animals (50 and 25)were administered white oil
**   by gavage at a dose of 5 ml/kg, every day during gestation
**   days 6 to 19 inclusive.  Food and water were available
**   continuously.  Animals were examined for viability and
**   clinical effects twice daily. Body weights were recorded on
**   days 0, 6, 10 and 20 of gestation.
**   On day 20 of gestation, all animals were euthanized with
**   methoxyfluorane and examined for gross changes. Each gravid
**   uterus was removed and weighed.  The number, location and
**   viability of each fetus and the number of implant sites were
**   recorded.  Fetuses were removed, weighed and the crown-rump
**   lengths measured.  All live and dead fetuses that had not
**   been resorbed were examined for external malformations.
**   Approximately half of the fetuses from each litter were
**   decapitated and the heads preserved for subsequent
**   examination for abnormalities.  The viscera were also
**   examined for malformations under low power magnification.
**   The remaining fetuses were stained with Alizarin red and
**   subsequently examined for skeletal abnormalities.
**   No organs, other than the uteri were weighed and no organs
**   were examined histologically in this study.
F008 IUC31
F020 3929
EOR
F002 40
F010 5.8.2
F004 1
F005 RE
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F006 McKee, R. H., Pasternak, S. J. and Traul, K. A. (1987)
** Developmental toxicity of EDS recycle solvent and fuel oil.
** Toxicology Vol 46, pp 205-215
F007 McKee, R. H., Pasternak, S. J. and Traul, K. A. (1987)
** Developmental toxicity of EDS recycle solvent and fuel oil.
** Toxicology Vol 46, pp 205-215
F008 IUC31
F020 3930
EOR
F002 40
F010 5.8.2
F004 1
F005 RL
F006 Although there were no untreated animals for comparison, the
** results were nevertheless, considered to be within normal
** limits. Consequently, the study is useful in providing
** evidence of the lack of developmental effects for white oil.
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** results were nevertheless, considered to be within normal
** limits. Consequently, the study is useful in providing
** evidence of the lack of developmental effects for white oil.
F008 IUC31
F020 3931
EOR
F002 40
F010 5.8.2
F004 1
F005 RM
F006 White oil was used as the solvent control in two separate
** studies, one for each of two test materials.
** This summary only reports on the outcome of the animals in
** the two control groups.
**
** The CAS# for the material that was used in this stud
F007 White oil was used as the solvent control in two separate
** studies, one for each of two test materials.
** This summary only reports on the outcome of the animals in
** the two control groups.
**
** The CAS# for the material that was used in this study is not included in
* the Lubricating Base Stocks category. However, because white oils are so
* highly purified, toxicologically and compositionally they are all very
* similar. Therefore, the Testing Group thinks the results on CAS #
* 8012-95-1 are applicable to the highly refined base oils that are
* included in this category.
F008 IUC31
F020 3932
EOR
F002 40
F010 5.8.2
F004 1
F005 RS
F006 One animal died in the control group containing 50 animals
** and this was attributable to misdosing.
** Increases in body weight during the study were considered
** normal. These with other recorded parameters are
** summarized in the table below.

**
**
**   D
F007 One animal died in the control group containing 50 animals
**   and this was attributable to misdosing.
**   Increases in body weight during the study were considered
**   normal. These with other recorded parameters are
**   summarized in the table below.
**
**

** Day of gestation	Group 1 (25 rats)	Group 2 (50 rats)
** Body weights (g)		
** 0	207.2	225.4
** 6	227.5	248
** 10	235.9	259.3
** 15	260	284.3
** 20	329.1	351.9
** Uterine wt	67.2	70.7
** Number of litters	25	49
** Implants/litter	11.3	12.0
** Resorptions/litter	0.06	0.47
** Males		
** No./litter	5.12	5.96
** Crown-rump length (mm)	3.66	3.6
** Wt. of fetuses	4.26	4.23
** Females		
** No./litter	5.6	5.61
** Crown-rump length (mm)	3.61	3.52
** Wt. of fetuses	4.02	4.07

**
**   In the control group containing 50 animals, 3 malformed
**   fetuses were found in 3 litters; one had an extra lumbar
**   vertebra, one had a discrete area of ossification in the
**   area
**   of the junction of the frontal and nasal bones, one had
**   moderately dilated lateral ventricles of the brain.
**
**   3 malformed fetuses were also found in 3 litters of the
**   other control group. These were, a vertebral arterial canal
**   of a cervical process fully ossified in 2 fetuses and
**   angulated ribs in a third fetus.
**
**   The authors considered these malformations to be minor and
**   that the findings were within the normal ranges for the
**   strain of rat.
F008 IUC31
F020 3933
EOB
C
X